QuikRead go® HbA1c: a competitive, reliable, and easy-to-use point of care test to aid decisions in treatment and diagnosis of diabetes mellitus

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Introduction

Quantitative measurement of glycated haemoglobin (HbA1c) concentration is an established method for monitoring long-term blood glucose control in individuals with diabetes mellitus[1-3]. In addition, HbA1c concentration can be used to aid the identification of individuals who may be at risk of developing diabetes mellitus as well as support the diagnosis of the condition[4].

Measuring HbA1c at the point of care (POC) offers an opportunity to further improve diabetes care; the HbA1c results are ready to be discussed during the patient consultation enabling immediate modifications to the treatment as required[5,6]. HbA1c POC testing also facilitates patient satisfaction, motivation and education[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 QuikRead go® Instrument.

The aim was to study the reliability of the QuikRead go HbA1c POC test among several reagent lots, as well as to assess the usability of the test. In addition, the performance of the test was compared to three other commercial HbA1c POC tests and an IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) calibrated reference method.

Methods

The method comparison was performed between QuikRead go and three commercial HbA1c POC methods: A (Alere Afinion™, Abbott Park, IL, USA), B (DCA Vantage™, Siemens Healthcare Diagnostics Inc., Germany) and C (cobas b 101, Roche Diagnostics, Germany). 103 venous whole blood samples with respective reference values of 25–103 mmol/mol were measured as single replicates with each POC method according to their instructions for use. Relative bias (RB), i.e. the relative deviation of a result from its reference value, was calculated for each measurement. Average absolute relative bias (ARB), i.e. the average of the RB absolute values, and the median ARB were calculated to characterize the performance of the POC methods.

For the reagent lot variation analysis 24 venous whole blood samples (29–103 mmol/mol) were measured as single replicates with six QuikRead go HbA1c test lots. The data was analysed by comparing the RB values of the lots to one another.

The largest allowable ARB between results and corresponding reference values was set to 10 %, which is the largest allowable total error for the test system[7,8]. Pearson correlation coefficient was calculated for each method and QuikRead go HbA1c test lot to study correlation with the reference method. The secondary reference method used was an IFCC calibrated HbA1c Tosoh G8 (Tosoh Bioscience, Belgium) and the blood samples used were obtained from ERL, the European Reference Laboratory for Glycohaemoglobin (Location Isala, Zwolle, The Netherlands). Testing was carried out according to CLSI EP09C-3rd edition.

Customer experience was investigated with a survey performed on health care professionals (n=24) using the QuikRead go HbA1c test.

Results

All four POC methods had average and median ARBs under the 10 % allowable difference mark. Across the whole measuring range 96 % of measurements on the QuikRead go had an ARB of less than 10 % while method A was at 95 %, B at 80 %, and C at 98 %. A quality target was set to 5 % ARB and was reached by ARB averages of QuikRead go as well as methods A and C. In addition, 90 % of measurements on the QuikRead go and 45–85 % on the three other methods compared reached the 5 % quality target in the clinically significant HbA1c concentration range, 45–55 mmol/mol. The RBs are visualized by boxplots in figures 1A and 1B. Correlation to the reference method was similar among QuikRead go and methods A and C with coefficients of 0.993-0.994. The main results of the method comparison are presented in table 1.

In the QuikRead go HbA1c lot comparison, 99 % of the total 144 measurements had a difference of less than 5 % to the IFCC reference method across all lots. The two measurements outside the performance goal were from lot 2 and had RBs of -5.3 % and -6.0 %. All measurements were within the 10 % ARB acceptance range. The difference plot (Bland-Altman) of all measurements in the lot variation testing is shown in figure 2. All tested reagent lots had excellent correlation to the reference method with correlation coefficients of 0.996–0.999.

The average response to the customer survey was 4.4/5.0 for both the ease of testing and ease of sample collector use, and 4.2/5.0 for the question would the user recommend the test to a colleague.

Table 1. Results of method comparison between QuikRead go and three other commercial HbA1c POC tests (POC A, B, and C).

	QuikRead go	POC A: Alere Afinion	POC B : DCA Vantage	POC C : cobas b 101
Concentration range 25–103 mmol/mol n = 103				
Average ARB* (%)	3.0	3.2	6.1	2.7
Median ARB* (%)	2.6	2.6	5.7	2.4
Pearson correlation coefficient to reference method	0.993	0.993	0.986	0.994
Measurements with ARB* ≤ 10 %	n = 99 (96 %)	n = 98 (95 %)	n = 82 (80 %)	n = 101 (98 %)
Concentration range 45–55 mmol/mol n = 20				
Measurements with ARB* ≤ 10 %	n = 19 (95 %)	n = 20 (100 %)	n = 18 (90 %)	n = 20 (100 %)

*ARB: absolute value of the relative bias to the reference method

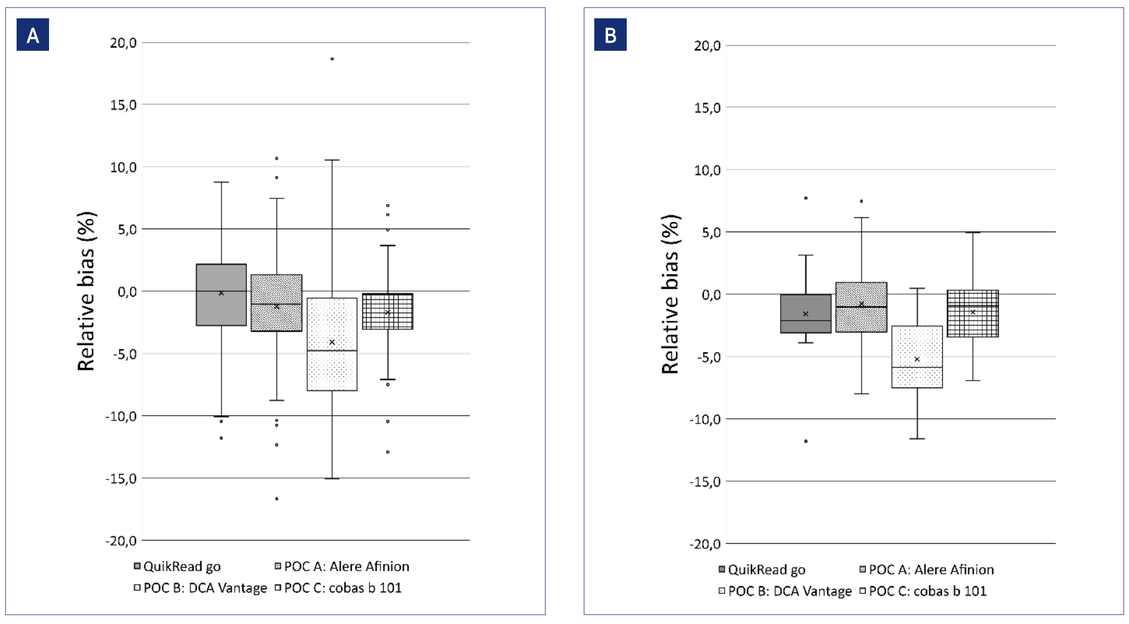

Figure 1. Box plots of method comparison relative biases to the IFCC reference method in HbA1c range 25–103 mmol/mol (n = 103) (A), and 45–55 mmol/mol (n = 20) (B). Box: IQR (Q3-Q1); middle line: Q2, median; ×: mean; whiskers: minimum and maximum excl. outliers; dots: outliers, limit Q1–1.5 * IQR, or Q3 + 1.5 * IQR

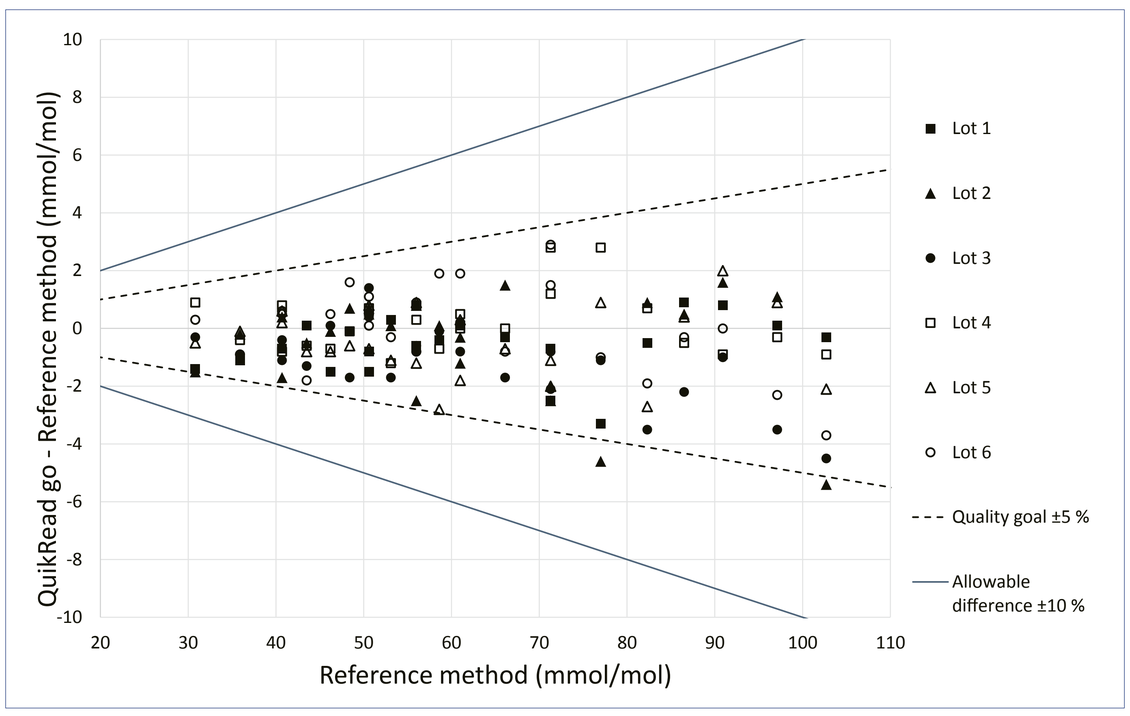

Figure 2. Difference (Bland-Altman) plot of six QuikRead go HbA1c test lots, and the IFCC reference method values. Allowable difference: ±10 %; quality target: ±5 % (from reference method).

Conclusions

The results of the method comparison and customer investigation indicate that QuikRead go HbA1c is easy to use and highly competitive among tested commercial HbA1c POC tests. The tested QuikRead go HbA1c reagent lots showed corresponding performance in terms of correlation and difference to IFCC reference method.

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