QuikRead go HbA1c test shows good performance with patient samples when compared to IFCC and NGSP certified Secondary Reference Measurement Procedure methods

L Teirilä[1], L Orivuori[1], L Meriläinen[1], H Peltoniemi[1], N Ristiniemi[1] and K Kurppa[1]

[1] Aidian Oy, Espoo, Finland

Introduction

Measurement of glycated hemoglobin (HbA1c) concentration at the point-of-care (POC) is important in the diagnosis of diabetes and identification of patients at risk for developing diabetes mellitus[1]. Quantitative measurement of HbA1c concentration is an established method for monitoring long-term blood glucose levels in individuals with diabetes[2–4]. HbA1c test is also convenient for the patient since it does not require fasting. Measuring at the POC brings valuable aspects to the treatment process: HbA1c result can be immediately discussed with the patient which leads to improved over-all result of care with increased patient satisfaction and self-motivation. Importantly, the possible treatment modification can be performed during the same visit[1].

QuikRead go HbA1c test 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 performed with the portable QuikRead go instrument. The aim of the study was to compare QuikRead go HbA1c test to four IFCC and NGSP certified Secondary Reference Measurement Procedure (SRMP) methods and show the test performance in patient samples.

Methods

The imprecision for the QuikRead go HbA1c assay was investigated based on the CLSI EP-15 protocol. Five replicates per day were measured from three fresh patient samples (HbA1c values of 30, 48 and 75 mmol/mol) on five consecutive days. The CVs in EP-9 were based on duplicates with fresh patient samples.

The accuracy of the QuikRead go HbA1c assay was evaluated by a method comparison to four IFCC and NGSP certified Secondary Reference Measurement Procedures, SRMPs (1. Abbott Enzymatic method on Alinity, Abbott 2. Premier Hb9210, affinity chromatography HPLC, Trinity Biotech 3. Roche Tina-quant HbA1c Gen. 3 on Cobas c513, Roche Diagnostics 4. Tosoh G8, cation-exchange HPLC, Tosoh Bioscience) according to the CLSI EP-9 protocol. In total, 40 fresh venous whole blood samples, which had the range of HbA1c values in 30–90 mmol/mol, were analyzed. Eight samples were measured per day as duplicates on five days.

The linear regressions (Weighted Deming[5]) were calculated using R programming language, version 4.1.2.

Results

The results of imprecision analysis obtained by EP-15 with three level of fresh patient samples are shown in table 1. CV at an HbA1c value of 74.0 mmol/mol was 2.2% in SI units, and 1.7% in NGSP units. The CVs at HbA1c values of 41.7 mmol/mol and 30.8 mmol/mol were 3.2% in SI units and 2.0% in NGSP units and 4.3% in SI units and 2.4% in NGSP units, respectively. The CVs based on the duplicates in EP-9 for the QuikRead go HbA1c test lot were 1.8 in SI units, and 1.3 in NGSP units.

The results of the method comparison are shown as Weighted Deming regression parameters between QuikRead go HbA1c and SRMPs in Table 2. The regression lines comparing QuikRead go HbA1c to Abbott Enzymatic on Alinity, Premier Hb9210, Roche Tina-quant Gen. 3, and Tosoh G8 are presented in figures 1–4, respectively. QuikRead go HbA1c had the correlation $r \geq 0.99$ to all compared SRMPs. The method 2., Premier Hb9210, was the closest to QuikRead go HbA1c in this data set. Maximum two samples of QuikRead go HbA1c exceeded the bias of 10 % in these performed method comparisons.

Table 1. Results of precision analysis

QuikRead go HbA1c	CV (%) SI units	CV (%) NGSP units
EP-9	1.8	1.3
EP-15	4.3 (30.8. mmol/mol)	2.4 (4.97%)
	3.2 (41.7 mmol/mol)	2.0 (5.97%)
	2.2 (74.0 mmol/mol)	1.7 (8.92%)

Table 2. Weighted Deming regression line parameters when comparing QuikRead go HbA1c to Secondary Reference Measurement Procedures, SRMPs, 1.–4.

Method	Slope	Intercept	Correlation (Pearson)
SRMP 1., Abbott Enzymatic on Alinity	1.07	-3.01	0.99
SRMP 2., Premier Hb9210	1.01	-0.71	0.99
SRMP 3., Roche Tina-quant Gen. 3	1.05	-2.80	0.99
SRMP 4., Tosoh G8	1.05	-2.90	0.99

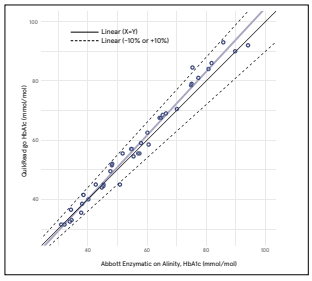

Figure 1. QuikRead go HbA1c and Abbott Enzymatic on Alinity comparison with fitted Weighted Deming regression.

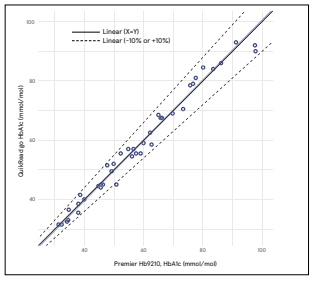

Figure 2. QuikRead go HbA1c and Premier Hb9210 comparison with fitted Weighted Deming regression.

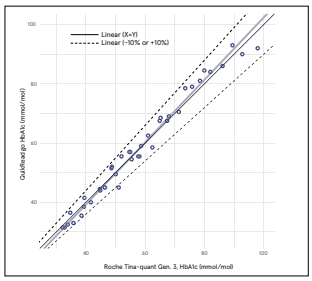

Figure 3. QuikRead go HbA1c and Roche Tina-quant Gen. 3 comparison with fitted Weighted Deming regression.

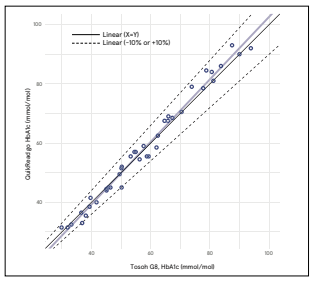

Figure 4. QuikRead go HbA1c and Tosoh G8 comparison with fitted Weighted Deming regression.

Conclusions

The results of this study show that QuikRead go HbA1c is standardized and very well comparable to established IFCC and NGSP reference methods. Results at the clinically relevant HbA1c levels showed the best precision according to IFCC and NGSP qualification criteria[3,6]. In addition, QuikRead go HbA1c shows repeatable results from patient samples which indicates that QuikRead go is a reliable and effective method for the quantitative determination of HbA1c in the POC.

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