

Introduction

- Measurement of HbA_{1c} is used to monitor diabetes control and has also recently been recommended as a method of diagnosis of diabetes by the ADA [1], WHO [2] and IDF [3] as an alternative to the oral glucose tolerance test.
- Point of care testing (POCT) is performed on site, often while the patient is still in the clinical setting and allows clinical decisions to be made in real time, without the need to wait for laboratory results.
- POCT in the measurement of HbA_{1c} has been performed for a number of years, but not always with the level of performance required for clinical decision making.

Point of Care Analysers

The Quo-Test and Quo-Lab HbA_{1c} analysers utilise boronate fluorescence technology which is interference free. Results are available with 4 minutes.

Quo-Test



Quo-Lab



Aim

The aim of this study was to compare the performance of the fully automated Quo-Test and semi-automated Quo-Lab POCT HbA_{1c} analysers (EKF Diagnostics) with an established laboratory HPLC method (D10, BioRad).

Methods

- Blood samples (n=50) from non-diabetic and diabetic subjects were collected into EDTA.
- HbA_{1c} was determined using the BioRad D10 HPLC analyser as the reference method.
- 4µL of the same sample was assayed on both POCT analysers.
- Intra-assay variation was determined by running low, medium and high level HbA_{1c} samples in triplicate.
- Inter-assay variation was determined by assaying an elevated control sample on 5 different days.
- External Quality Assurance (EQA) samples were also run on both POCT analysers and compared to the overall, all methods mean score.

Results

Fig 1: Comparison of Quo-Test (A) and Quo-Lab (B) with reference HPLC method

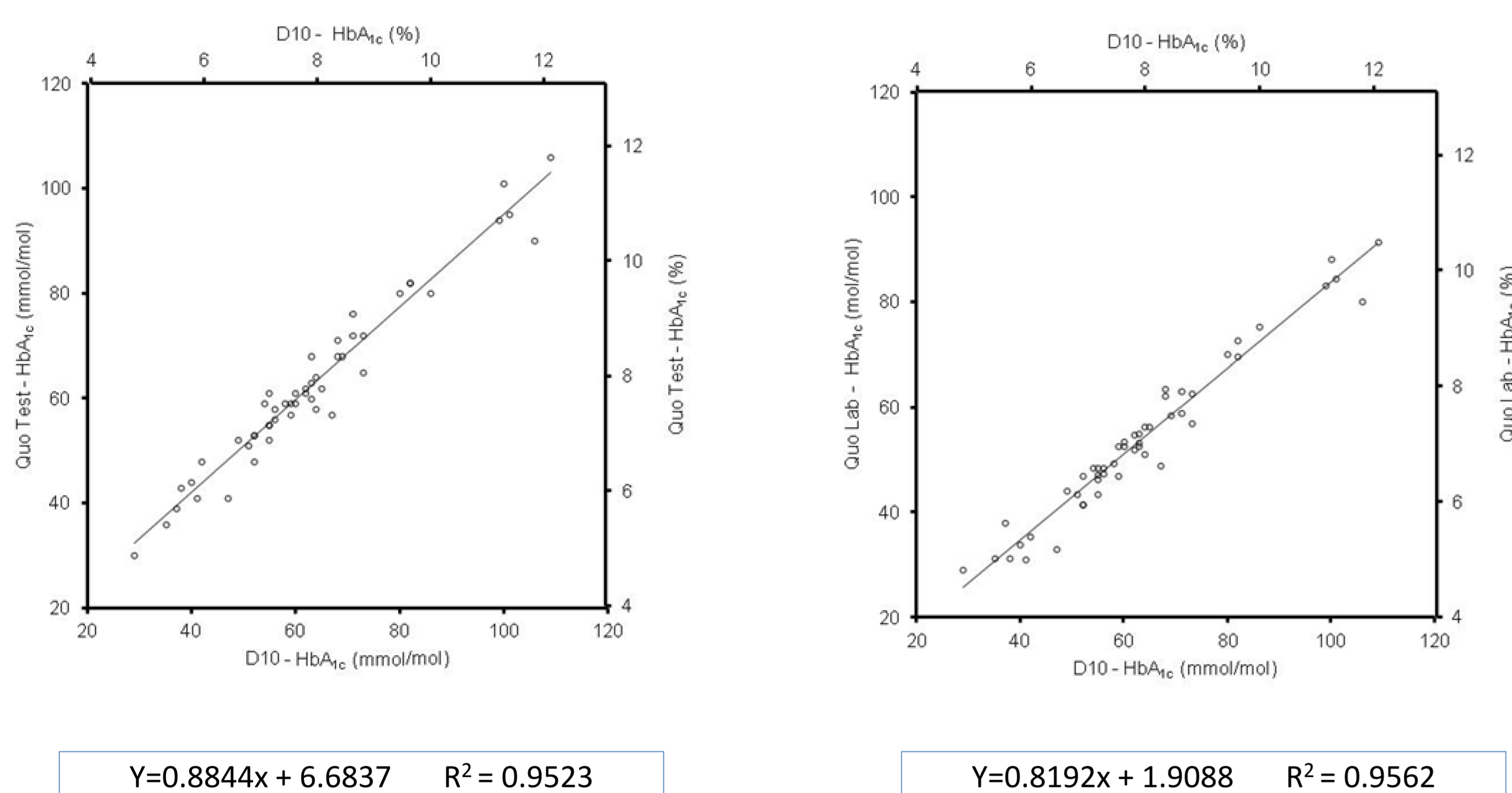


Fig 2: Difference plots of Quo-Test (C) and Quo-Lab (D) with reference HPLC method

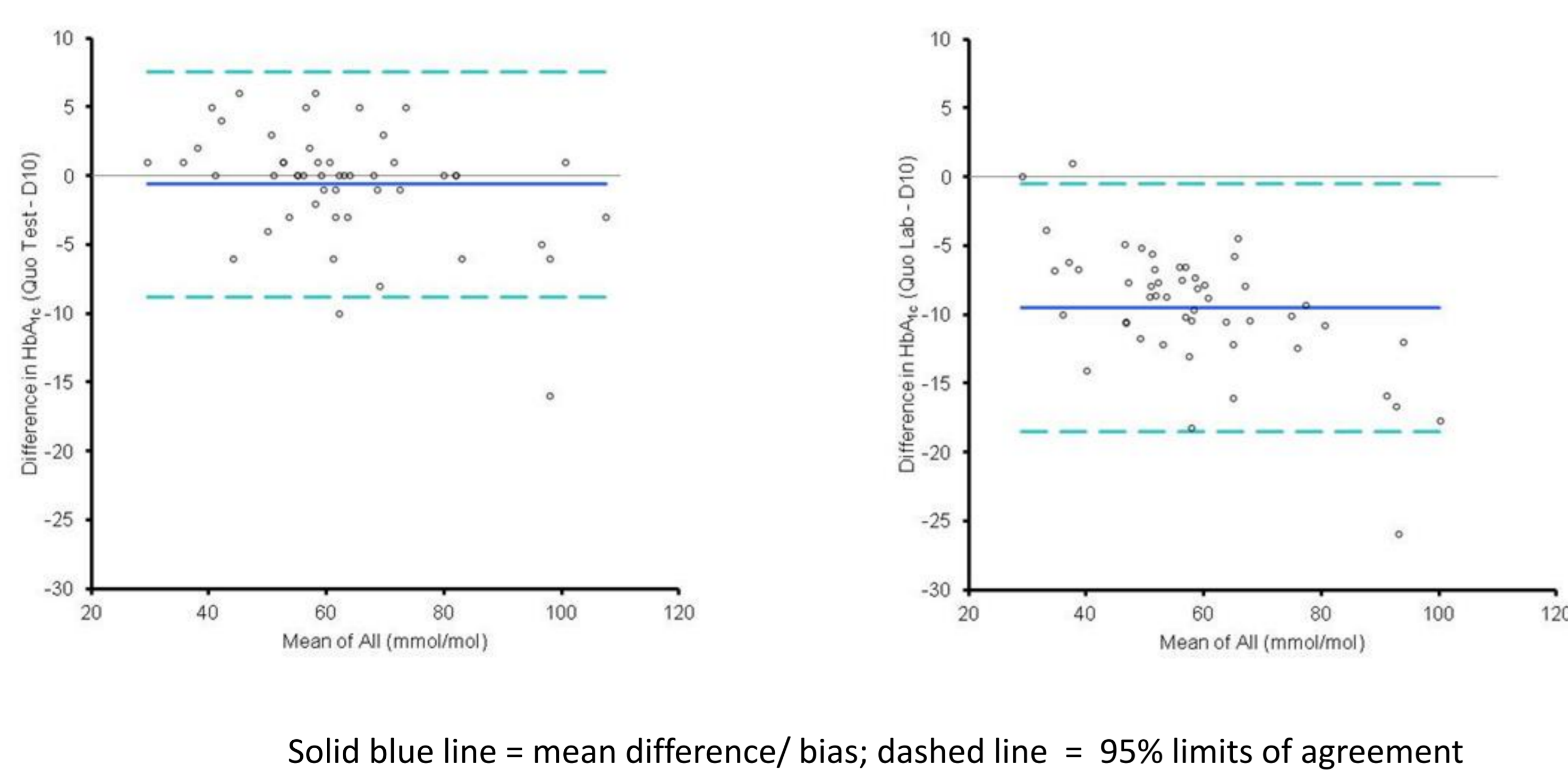


Table 1: Assay precision

		n=	Mean HbA _{1c} (mmol/mol / %)	%CV
Quo-Test	Intra-	3	42.0 / 6.0	2.4 / 1.0
		3	60.7 / 7.7	6.7 / 5.3
		3	96.0 / 10.9	1.8 / 1.6
	Inter-	5	88.8 / 10.3	10.4 / 8.0
		3	32.7 / 5.1	5.1 / 1.9
		3	54.0 / 7.1	6.7 / 5.1
Quo-Lab	Intra-	3	86.3 / 10.0	0.8 / 0.6
		3	73.2 / 8.8	2.2 / 1.9
		5	73.2 / 8.8	2.2 / 1.9
	Inter-	5	35.5 / 5.4	2.2 / 1.3
		5	46.0 / 6.4	2.7 / 1.8
		5	68.1 / 8.4	2.1 / 1.6
D10	Inter-	5	84.8 / 9.9	1.7 / 1.5
		5	84.8 / 9.9	1.7 / 1.5
		5	84.8 / 9.9	1.7 / 1.5

Table 2: Mean EQA cycle scores

Cycle	Quo-Test	Quo-Lab	Overall WEQAS mean	No of labs
A	56.0	44.8	50.7	271
B	56.7	47.6	48.8	150
C	63.5	56.9	64.3	214

Performance vs. EQA scheme overall mean (3 cycles)

Quo-Test: R² = 0.8765 Quo-Lab: R² = 0.9581

Discussion

- Agreement between the two POCT analysers with an established HPLC reference method was good across a wide range of HbA_{1c}, although a negative bias was observed for the Quo-Lab POCT analyser
- Use of the Quo-Test and Quo-Lab POCT analysers provides a rapid, accurate and reproducible method of determination of HbA_{1c}
- Both POCT analysers have the benefit of being able to generate results immediately in the clinical setting, providing greater convenience to the patient.

References

- 1 American Diabetes Association. Diagnosis and classification of diabetes mellitus. Diabetes Care 2010;33 Suppl 1:S62–S69.
- 2 Use of Glycated Haemoglobin (HbA_{1c}) in the Diagnosis of Diabetes Mellitus. Abbreviated Report of a WHO Consultation. Geneva. World Health Organization 2011.
- 3 International Diabetes Federation Clinical Guidelines Task Force. Global Guideline for Type 2 Diabetes 2012;9–14.

