MyHealthTest HbA1c Dried Blood Spot Test Technical Monograph

Diabetes is a major health problem with significant morbidity and mortality. The AusDiab study of over 11,000 participants aged from 25 years of age found the incidence of diabetes to be 7.4% with 50% of cases being previously undiagnosed.[1] The HbA1c (glycated haemoglobin) level is commonly measured in the management of diabetes and more recently has been used for the diagnosis of diabetes. It is now approved for reimbursement in the diagnosis of diabetes in Australia.

Dried blood spot (DBS) testing was first introduced into the literature in 1913[2] and began to be widely used from 1963 with the publication of Guthrie and Susi's[3] work and is now routinely used in heel-prick sampling of newborn infants. There is now a wide body of literature describing the use of DBS for measuring a range of analytes, including HbA1c.

In 2014 researchers at the John Curtin School of Medical Research at the Australian National University (ANU) conducted a comparative study of HbA1c levels in dried blood spots versus venous whole blood. In total 115 volunteers were sampled, including 11 people with previous diagnosis of type 1 diabetes and 56 with previous diagnosis of type 2 diabetes. Results were compared between venous whole blood samples analysed on day 0 and capillary dried blood spot samples collected with the MyHealthTest dried blood spot collection kit analysed on days 0, 4, and 7 after collection. Correction formulae were derived and applied to raw dried blood spot results to allow for capillary versus venous blood and matrix effects. The demographics of the sample population are outlined in Table 1.

Study Population

Table 1 – Population Characteristics

	All	No Diabetes	Type 1 Diabetes	Type 2 Diabetes
Gender	51M:64F	20M:28F	2M:9F	28M:28F
Age (years; mean)	55.9	46.2	45.0	64.8
Whole Blood HbA1c (%) mean±SD	6.22±1.11	5.41±0.35	7.80±0.81	6.61±1.11

SD=standard deviation

Results

Whole blood and dried blood spot samples (capillary and venous) were measured in duplicates or triplicates, and correction formulae derived and applied. The intra-assay coefficients of variation (CV) were then determined. The median CV of the dried blood spot samples was less than 2.3 for all days under examination, demonstrating the precision of capillary dried blood spot testing for HbA1c measurement. Mean and standard deviations of HbA1c levels in whole blood and dried blood spots were calculated and no significant difference between the two groups was detected.

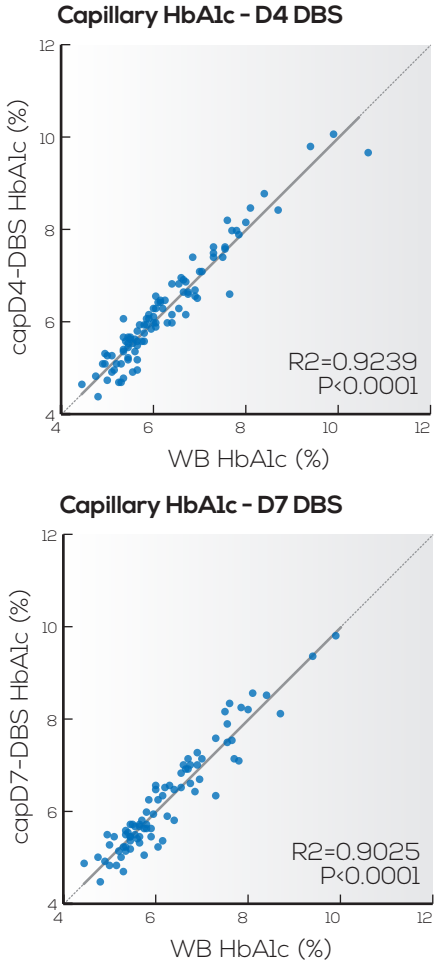
Table 2 – Mean, standard deviation and intra-assay coefficient of variation for whole blood (WB) on Day 0 and dried blood spot (DBS) on Day 0, 4 and 7.

	Day	HbA1c % (mean, SD)	Intra-assay CV % (median)
WB	0	6.22 ± 1.11	1.19
DBS	0	6.39 ± 1.17	2.28
	4	6.26 ± 1.17	2.28
	7	6.25 ± 1.15	1.98

There was a high correlation between the HbA1c levels from capillary dried blood spot samples extracted and analysed on Day 4 and Day 7 and HbA1c levels from venous whole blood samples analysed on Day 0. These results were plotted on linear regression graphs in Figure 2 illustrating the high levels of correlation (R^2 > 0.90 for all days).

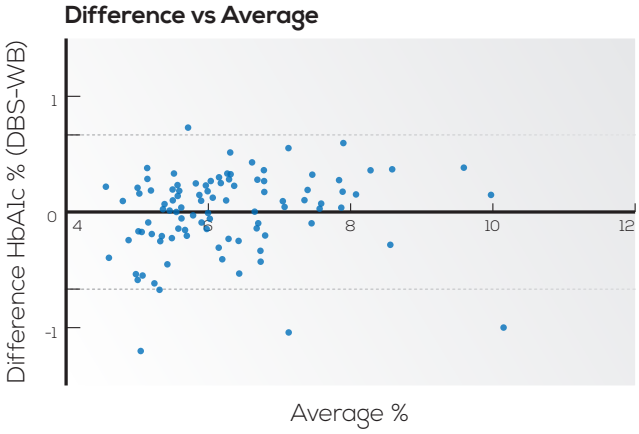
[1] Dunstan DW, Zimmet PZ, Welborn TA, et al. The rising prevalence of diabetes and impaired glucose tolerance: the Australian Diabetes, Obesity and Lifestyle Study. Diabetes Care 2002; 25: 829-834.
[2] Bang I: Ein verfahren zur mikrobestimmung von blutbestandteilen. Biochem Ztschr 1913, 49:19-39.
[3] A Simple Phenylalanine Method for Detecting Phenylketonuria in Large Populations of Newborn Infants, by Robert Guthrie and Ada Susi, Pediatrics, 1963;32:318-343.

Figure 2 – Linear regression of corrected capillary dried blood spot samples from days 4 and 7



The Bland-Altman plot is used to measure the difference between two assays. In this case the capillary DBS method is plotted against traditional whole blood samples. The test for days 4 and 7 revealed a bias approaching zero with limits of agreement less than 1.

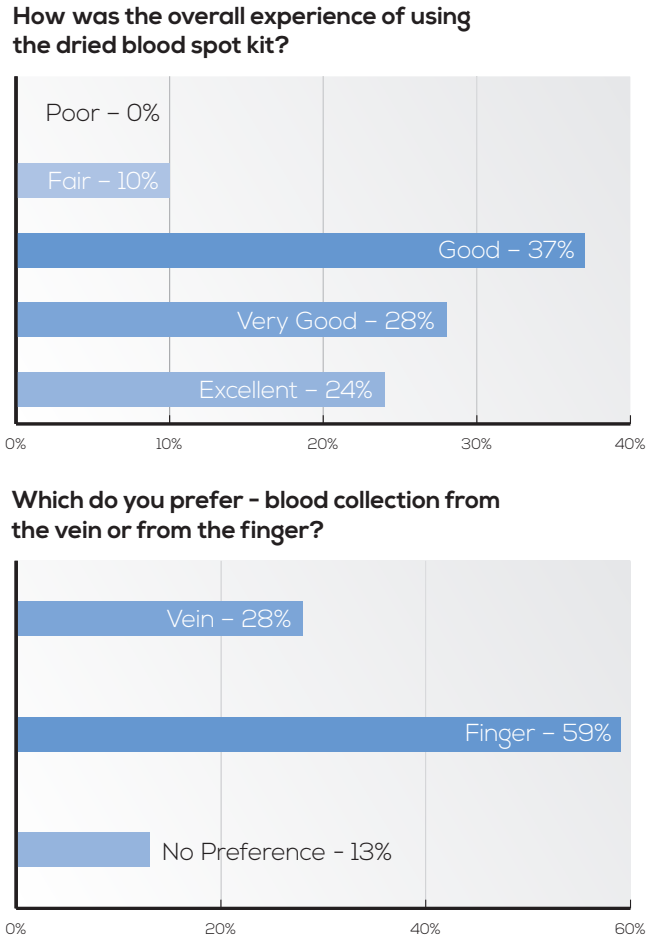
Figure 3 - The Bland-Altman plot illustratings the high level of correlation between the two methods of HbA1c sample collection – corrected capillary dried blood spot and venous whole blood samples on Day 4.



Participant feedback

Study participants were asked to collect their own dried blood spot samples using the MyHealthTest dried blood spot collection kit, and had venous samples collected by an experienced phlebotomist. 73 participants then rated their experience with capillary blood sample collection. 89% rated capillary blood sampling with the kit as good, very good or excellent. 59% stated a preference for finger-prick sampling at home versus 28% that prefer traditional venous sampling. Results are shown in Figure 4.

Figure 4 - Study participant feedback



Conclusion

Dried blood spots provide a viable alternative to venous whole blood sampling with no significant difference in derived results. Testing precision is high with a low coefficient of variation. Dried blood spot sampling was found to be highly acceptable to study participants and was strongly preferred over traditional venepuncture.

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