

# The HbA1c Evaluation of the Afinion™ AS100 Analyzer for Point-of-Care use in comparison to the DCA 2000 and the Variant Turbo<sup>1</sup>

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## Purpose

The HbA1c evaluation conducted at Baystate Medical Center in January and February 2007 included 3 parts: Precision, Accuracy, and Method Comparison of the Afinion™ AS100 Analyzer, DCA 2000, and the Variant Turbo. The two main objectives of the study was to demonstrate that the precision and accuracy of the Afinion™ AS100 Analyzer's HbA1c assay were clinically acceptable and to demonstrate the level of correlation between the Afinion™ AS100 Analyzer, DCA 2000, and the Variant Turbo.

## Precision

The precision study involved performance of 3 patient and 2 control samples in duplicate, twice per day for a total of 10 days. The Afinion's precision was better than the comparative POCT device DCA 2000, and compared well with the core laboratory HPLC, the Variant Turbo.

	% CV	Range of HbA1c Values
Afinion™ AS100 Analyzer	0.9 - 1.8%	5.4-8.4%
DCA 2000	2.9 - 3.3%	5.2-10.3%
Variant Turbo	1.1 - 1.9%	5.6-9.6%

## Accuracy

Accuracy was evaluated by analysis of 6 samples from the National Glycosylated Hemoglobin Standardization Program (NGSP) over a 3 day period.

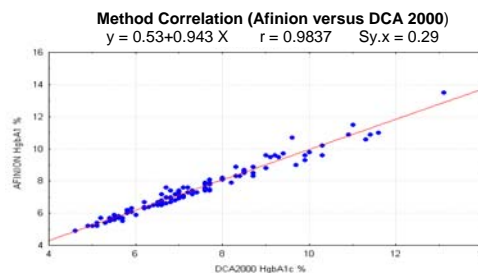
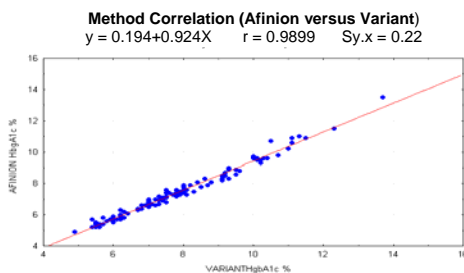
- o The data demonstrates that the Variant Turbo read closest to NGSP calibration, the DCA 2000 bias was lower, and the Afinion read between the two methods.
- o Precision of the NGSP samples were similar to that demonstrated with the patient samples in the precision part of the study.
- o The Afinion is not only able to exhibit laboratory quality performance but it is also accurate and reliable.

	Bias to NGSP Values		Reproducibility of NGSP Samples
	Average Unit	% Bias	
Afinion™ AS100 Analyzer	-0.23	-3.1%	0.8 - 2.9% CV
DCA 2000	-0.38	-4.9%	0 - 4.6% CV
Variant Turbo	-0.05 - +0.05	-0.5% - 1.1%	0 - 1.8% CV

## Method Comparison

Method comparison analyzed a total of 110 patient specimens collected in purple EDTA tubes (range of samples = 4.6 – 13.7 %HbA1c)<sup>2</sup> on all 3 analyzers. The data was analyzed by least squares regression and correlation statistics calculated.

- o Standard errors of estimate demonstrated that the Afinion compared well to the DCA 2000, but the spread of the data was tighter for the Afinion when compared to the Variant HPLC.
- o For a 2 standard deviation spread of the data across the range of results (95% of the data), the Afinion was within +/- 0.44 % HbA1c of the Variant and within +/- 0.58 % HbA1c of the DCA 2000.
- o On average, the Variant read higher than the DCA 2000, while the Afinion read between the two methods.



## Summary

In summary, the Afinion™ AS100 Analyzer performed remarkably well. The Afinion's precision and accuracy was better than the comparative POCT device (DCA 2000), and comparable to the gold standard (HPLC-Variant Turbo) for hemoglobin A1c analysis with minimal bias (<3% to the NGSP standardization program). Overall, the Afinion™ AS100 Analyzer correlated closer to the Variant HPLC method than the DCA 2000. The Afinion was accurate, precise, compared well with a core laboratory HPLC method, was easy to use, and we found the analysis time to be faster than the comparative POCT device (the DCA 2000).

<sup>1</sup> This study was deemed exempt from Institutional Review Board review on 12/12/2006 and utilized leftover specimens after laboratory analysis without patient identifiers.  
<sup>2</sup> All samples were analyzed by the three methods on the same day to minimize hemolysis and other variables.