Assessment of an Affinity Based Point of Care System for HbA_{1c}

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Abstract

Aim was to evaluate the analytical performance of a new Point of Care (POCT) system (Afinion™ AS100 Analyzer, Axis–Shield PoC AS, Oslo, N), based on boronate affinity chromatography. The system takes 3 min per test, requires 1.5 µL whole blood per analysis, does not suffer interference in presence of HbS and HbC, and reports National Glycohemoglobin Standardization Program (NGSP) aligned values.

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A total of 120 whole blood samples collected in EDTA and stored at +4 °C were analyzed within 2 days from collection. Ten out of the 120 samples were from patients under constant dialysis regimen. Two POCT systems, one immunochemical (Siemens DCA 2000+) and one affinity chromatography based (NycoCard® READER II, Axis Shield PoC AS), and two HPLC systems (Bio–Rad Variant II and Tosoh G7), all NGSP aligned, were used as comparison. Twenty–one out of the 120 samples (HbA_{1c} range 4.6–12.0 %) were measured in duplicate, in order to evaluate analytical imprecision by the method of the differences between duplicates. Three different batches of Afinion™ HbA_{1c} reagents were evaluated.

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Analytical imprecision (expressed in terms of CV, %) was: Afinion™, 1.0 % (mean HbA_{1c} 7.1 %); DCA 2000+, 1.5 % (HbA_{1c} 7.1 %); NycoCard®, 2.7 % (HbA_{1c} 7.2 %); Bio–Rad, 0.7 % (HbA_{1c} 7.3 %); Tosoh G7, 0.4 % (HbA_{1c} 7.4 %). From the analysis of the 110 samples from non–nephropatic patients the results of HbA_{1c} by Afinion™ (*y*–method) showed good correlation with all other methods, with the following linear regressions: y=0.819HbA_{1c} (DCA 2000)+1.2 (r=0.989); y=0.881HbA_{1c} (NycoCard®)+0.7 (r=0.976); y=0.856HbA_{1c} (Bio–Rad)+0.9 (r=0.974); y=0.783HbA_{1c} (Tosoh G7)+1.4 (r=0.977). On the average the Afinion™ results matched exactly the results by other methods at HbA_{1c} of 6.0 %, were slightly overestimated (+0.3 % on the average) at HbA_{1c} of 4.0 %, and were slightly underestimated (–0.4 %) at HbA_{1c} of 9.0 %. Such differences were constant in the three tested reagent batches. On 1 out of 10 samples collected from patients under constant dialysis regimen the results obtained by the Bio–Rad system gave poor resolution of the carbamylated hemoglobin fraction, which did not affect the HbA_{1c} results obtained by the other methods.

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The results obtained by the new POCT system meet the NACB guidelines for imprecision and accuracy. The method showed improved imprecision respect to the other POCT system (NycoCard®) produced by the same Company. The presence of carbamylated hemoglobin does not interfere in the measurement of HbA_{1c} by the Afinion™ method.

Imprecision

Table 1 reports the results on the imprecision, calculated from the differences of duplicates performed over one month of routine use. Twenty–one duplicate measurements were performed per each method.

Table 1. Imprecision of various HbA_{1c} methods.

Methods	*HbA_{1c}, %*		*CV, %*
	mean	*SD*	
POCT #1 (Afinion™)	7.08	0.07	1.0
POCT #2 (Nycocard®)	7.21	0.20	2.7
POCT #3 (DCA 2000+)	7.05	0.10	1.5
HPLC #1 (Tosoh G7)	7.41	0.03	0.4

Method comparison_1

Accuracy was assessed by analyzing simultaneously a number of blood samples (in EDTA) taken from the laboratory routine, and grouped as follows:
a) A total of 110 samples without renal disease.
b) A total of 10 samples from patients under constant renal dialysis.
Table 2 and Fig. 1 report the results on patients from group a.

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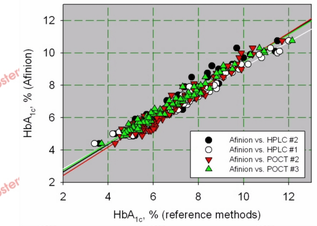
Table 2. Linear regression analysis of the intercomparisons between the Afinion™ method *(y–method)* vs. the other HbA_{1c} methods, used as reference.

Reference method (x–method)	*r*	*S_{yx}*	*Intercept ± ES*	*Slope ± ES*
POCT #2 (Nycocard)	0.976	0.31	0.667 ± 0.131	0.881 ± 0.019
POCT #3 (DCA 2000+)	0.989	0.24	1.205 ± 0.092	0.819 ± 0.014
HPLC #1 (Tosoh G7)	0.977	0.22	1.279 ± 0.082	0.783 ± 0.012
HPLC #2 (Bio–Rad Variant II)	0.974	0.33	0.931 ± 0.132	0.856 ± 0.019

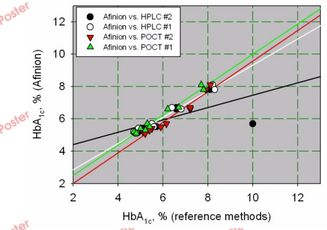
Method comparison_2

Fig. 1. Intercomparison between Afinion™ and other methods on blood samples from the laboratory routine.



Afinion™ data were found highly correlated to those from the other methods. However Afinion™ data were slightly biased respect to the other methods at low HbA_{1c} levels (+0.3 % on the average at 4.0 % HbA_{1c}) and at high HbA_{1c} level (–0.4 % at 9.0 % HbA_{1c}), with no bias at 6.0 % HbA_{1c}. This was confirmed in two other lots of test cartridges, as shown in Fig. 2, relatively just to one reference method. Similar data were obtained respect the other methods.

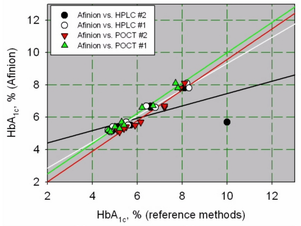
Fig. 2. Intercomparison between Afinion™ and one HPLC system with three different batches of Afinion™ reagents.



Method comparison_3

The results obtained on the analysis of blood samples from group b (patients under constant dialysis regimen) are shown in Fig. 3. On one out of ten samples the results obtained by one of the HPLC methods used as reference (Bio–Rad Variant II) were not correlated, because carbamylated hemoglobin was not resolved in the HPLC chromatogram.

Fig. 3. Intercomparison between Afinion™ and other methods on the analysis of 10 samples from patients under constant dialysis regimen.



Summary

Afinion™ in our hands was found robust and reproducible for measuring HbA_{1c}. The small bias was not significant to the clinical use, and within the actual goals of NACB guidelines. Error codes occurred only seldom, and were all related to the use of cartridges not brought to the room temperature before usage. We are glad to conclude that our evaluation meets the parallel evaluation recently performed by the Scandinavian evaluation of laboratory equipment for primary health care (SKUP), in which the Afinion™ test system was operated also by two nurses.

References

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3. www.SKUP.nu, accessed May 25, 2008.

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