Assessment of an Affinity Based Point of Care System for HbA1c

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Abstract

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

Table 1. Imprecision of Asian HbA1c methods.

Table 2. Method comparison - 2

Table 3. Method comparison - 3

Summary

Method comparison_2

Method comparison_3

References


Imprecision

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

Fig. 1. Intercomparison between Afinion™ and other methods on blood samples from patients under constant dialysis regimen.

The results obtained on the analysis of blood samples from group 1 (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.

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Table 2 and Fig. 1 report the results on patients from group a.

A total of 10 samples from patients under constant renal dialysis. Two POCT systems, one immunochemical (Afinion™ AS100 Analyzer, Axis−Shield PoC AS, Oslo, N), based on affinity chromatography methodology (Nycocard READER II, Avi 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 (HbA1c range 4.1−12.0 %) were measured in duplicate, in order to evaluate analytical imprecision by the method of the differences between duplicates. Twenty−one different batches of Afinion™ HbA1c reagents were evaluated.

A total of 120 whole blood samples collected in EDTA and stored at +4 °C were analyzed within 2 days from collection. Table 1 of the 120 samples were from patients under constant dialysis regimen. Two POCT systems, one immunochemical (Afinion™ AS100 Analyzer, Axis−Shield PoC AS, Oslo, N), based on affinity chromatography methodology (Nycocard READER II, Avi 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 (HbA1c range 4.1−12.0 %) were measured in duplicate, in order to evaluate analytical imprecision by the method of the differences between duplicates. Twenty−one different batches of Afinion™ HbA1c reagents were evaluated.

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