



The Point-of-Care (POC) A1CNow+: Precision and Accuracy of an Improved Version

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Introduction:

POC HbA1c testing can improve diabetes management. An easier-to-use model of the A1cNow+ POC device (Bayer Healthcare, US) has been released. It is NGSP (National Glycohemoglobin Standardization Program) certified for the measurement of HbA1c levels and is CLIA (Clinical Laboratory Improvements Amendments) waived for home use.

Figure 1. The improved A1cNow+ device. A fully integrated, disposable test cartridge device for quantification of HbA1c in capillary or venous blood.



Methods:

The study assessed the precision and accuracy of the new A1cNow+ device in comparison with another POC HbA1c testing device (DCA 2000, Siemens, Germany) and a HPLC reference laboratory method. Lithium-heparin full blood samples from 120 patients with diabetes (HbA1c range 5%-11%) were divided into aliquots for immediate precision and accuracy testing. Precision was assessed by calculating the coefficient of variation (CV) of repeat measurements (n=20) of four blood samples; two at normal (5.1% and 5.5%) and two at high (9.6% and 11.0%) HbA1c levels. Accuracy was assessed using correlation analysis to compare the HbA1c results of multiple blood samples over a wide HbA1c range obtained with the three assay systems.

Table 1. Precision comparison of the A1cNow+, DCA 2000 Analyser and BIO-RAD Diamat HPLC Analyser.

Blood sample HbA1c, %	Repetition of testing, n	A1cNow+ CV (%)	DCA 2000 CV (%)	HPLC CV (%)
5.5	20	3.6	2.3	2.0
5.1	20	2.75	2.1	1.98
9.6	20	3.07	2.4	2.12
11	20	7.2	3.1	2.2

CV=coefficient of variation

Figure 2. Accuracy comparison of the A1cNow+ and the DCA 2000 Analyser: Regression analysis.

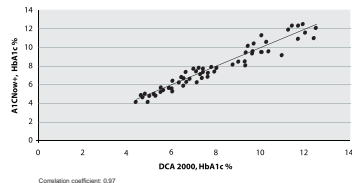
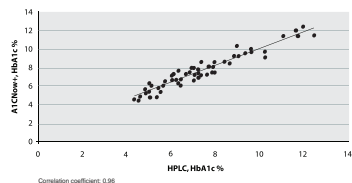


Figure 3. Accuracy comparison of the A1cNow+ and the HPLC method: Regression analysis.



Results:

CV's for the normal HbA1c level were 2.75% and 3.6% for the 5.1% and 5.5% HbA1c samples, respectively inside the NGSP guidelines (<5%). Examining a sample with a higher HbA1c (9.6%) the CV was 3.07%. Of note, using a sample (HbA1c 11.0%) from a patient carrying a variant hemoglobin the CV was 7.2%. The DCA 2000 and HPLC reference system were within NGSP guidelines at each HbA1c level tested. In accuracy testing, regression coefficients of 0.96 and 0.98 were obtained for comparison of the A1cNow+ with the HPLC and DCA 2000 systems, respectively.

Summary:

In conclusion, the A1cNow+ device, a low-investment cost and easy-to-use system for HbA1c monitoring, shows good precision and acceptable accuracy compared with the DCA 2000 and the gold standard of a HPLC method.