

Evaluation of HemoCue® HbA1c 501 System compared to Variant II (BioRad)

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Background and Aim

HbA1c concentration increases with rising blood glucose level. It is representative of the mean blood glucose level over the last two to three months and is therefore referred to as a long term indicator of diabetic/glucose control.¹ Better control of HbA1c leads to better outcomes in people with diabetes.² Therefore, it is recommended that patients with diabetes are monitored quarterly.³

In persons having hemoglobin variants such as HbS (sickle cell trait), HbC, HbE, HbD or an elevated level of fetal hemoglobin (HbF), some HbA1c methods can give inaccurate readings. This is of importance when treating patients with diabetes.⁴

The HemoCue HbA1c 501 System provides a method for measuring the percentage of HbA1c in both capillary and venous whole blood samples. The test is for point-of-care use to monitor glycemic control in patients with diabetes mellitus.

The objective of this study was to compare the performance of the HemoCue HbA1c 501 System to the KESLAB laboratory method, Variant II (BioRad), using venous blood patient samples. In addition, all samples were also analysed with DCA Vantage (Siemens).

Materials and Methods

All 88 samples included in the study were left over blood samples from the routine sampling procedure. These were analysed at KESLAB using all three methods; HemoCue HbA1c 501 System, BioRad Variant II and DCA Vantage. Additionally, twelve samples with various Hb variants were analysed. These samples were not included in the general calculations but are presented separately.

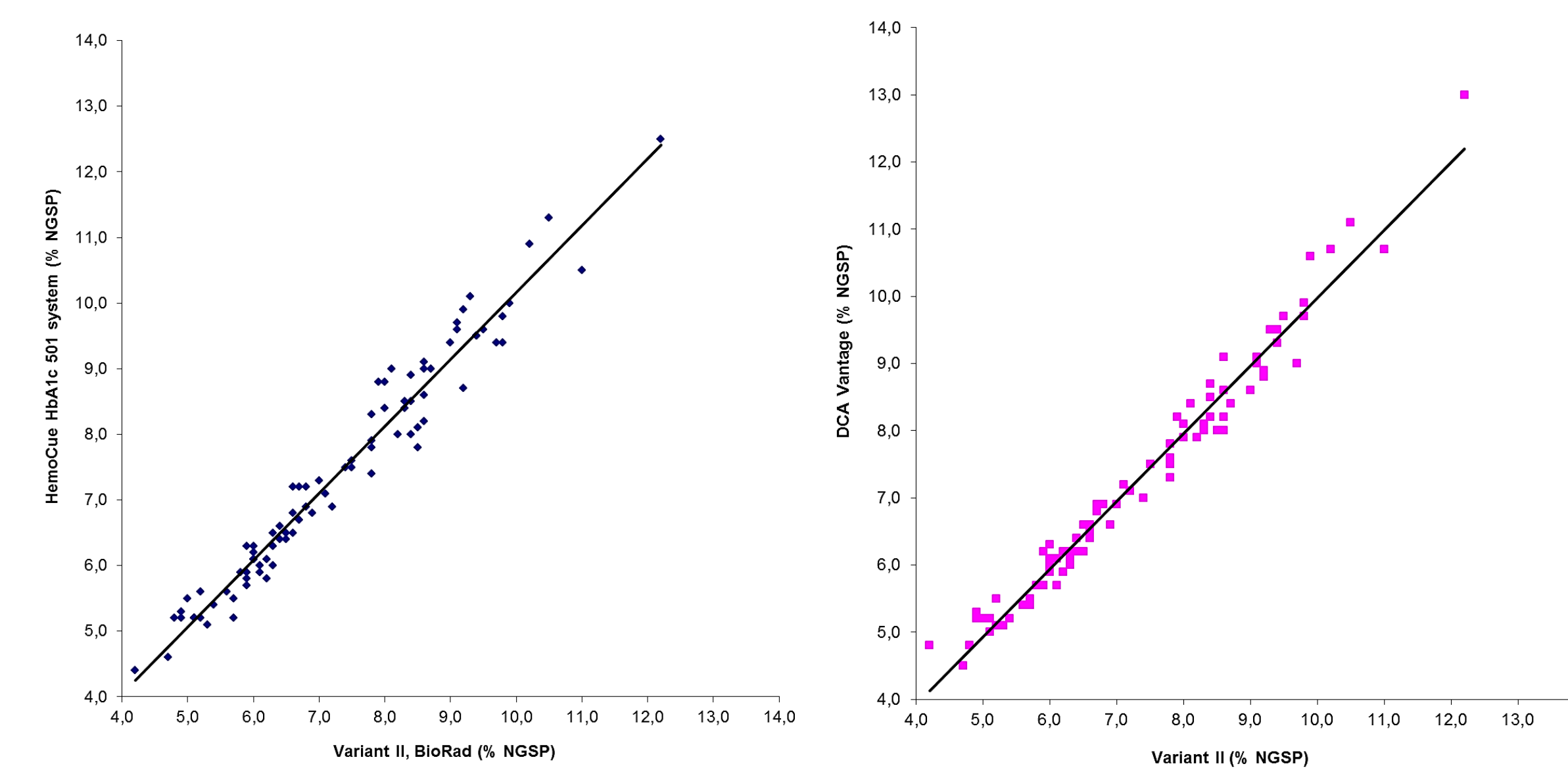


Figure 1a: Scatter plot for HemoCue HbA1c 501 (y) versus BioRad Variant II (x), % NGSP. $Y = 1,02x - 0,03$, $R = 0,980$. $N = 88$. **Figure 1b:** Scatter plot for DCA Vantage (y), versus BioRad Variant II (x). $Y = 1,007x - 0,098$, $R = 0,986$. $N = 88$.

Results

Linear regression analysis between the results from HemoCue HbA1c 501 System and BioRad Variant II produced the regression line: $y = 1,020x - 0,031$, $R = 0,980$. $N = 88$ (Figure 1a). Similar association was seen between DCA Vantage and Variant II: $y = 1,007x - 0,098$, $R = 0,986$. $N = 88$ (Figure 1b).

Almost half of the results on Hb variants measured with the BioRad Variant II system showed more than 7% difference compared to measurements made using HemoCue HbA1c 501 System and DCA Vantage. However, the number of samples with known Hb variants were limited and no actual conclusion could be made. Previous evaluations have demonstrated that different methods from BioRad have interference with Hb variants such as elevated levels of fetal Hb. Also, DCA Vantage has interference with fetal Hb when levels are increased by more than 10%.⁴

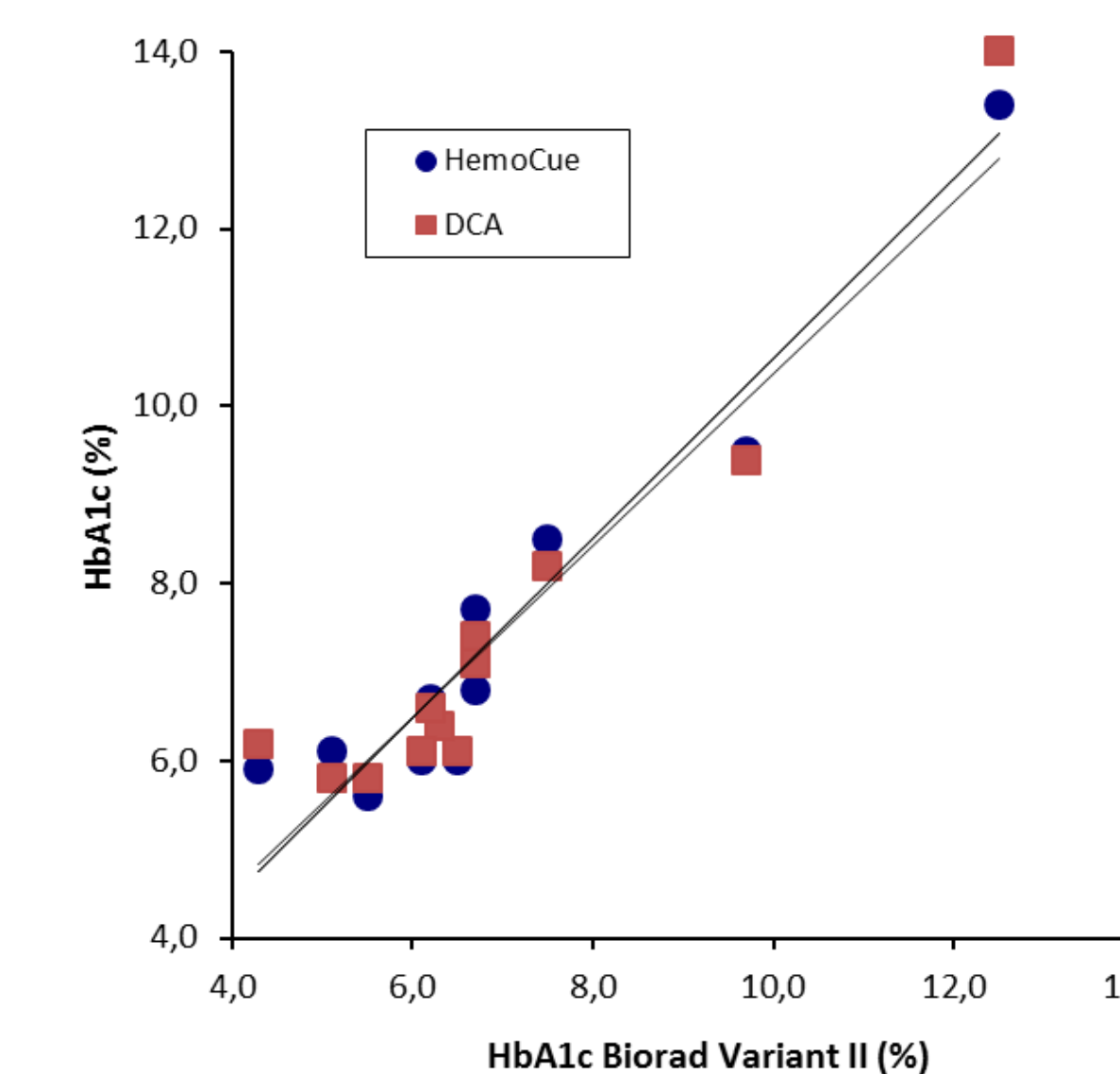


Figure 2: Scatter plot for samples with known Hb variants. HemoCue HbA1c 501 (y) versus BioRad Variant II (x), % NGSP. $Y = 0,9717x + 0,6544$, $R = 0,920$. $N = 12$. DCA Vantage (y) versus BioRad Variant II (x), % NGSP. $Y = 1,0152x + 0,3946$, $R = 0,917$. $N = 12$.

Summary

In this study we have evaluated the HemoCue HbA1c 501 System and compared it with the laboratory method Variant II (BioRad). The systems show good agreement in a broad range of glycemia. According to KESLAB, the usability of the HemoCue HbA1c 501 System is good. Additionally, all samples in the study were also analysed with DCA Vantage (Siemens). Even this system showed good correlation to Variant II.

References:

- 1) <http://www.diabetes.co.uk/what-is-hba1c.html>
- 2) The Diabetes Control and Complications Trial (DCCT) Research Group. The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. New England Journal of Medicine, 1993; 329: 977 – 986.
- 3) Executive Summary: Standards of Medical Care in Diabetes – 2012. Diabetes Care, Vol 35, Suppl 1, January 2012.
- 4) <http://www.ngsp.org/index.asp>