

Evaluation of HemoCue HbA1c 501 system

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Background and Aim:

HbA1c is widely used as the most important marker for routine monitoring of long-term glycemic status in patients with diabetes^{1, 2}. The use of point-of-care testing (POCT) for HbA1c provides the opportunity for more timely treatment changes. Better control of HbA1c leads to better outcomes in people with diabetes^{1, 2}.

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 perform an evaluation by the intended user. The evaluation includes two parts; 1) a method comparison between HemoCue HbA1c 501 and Roche Cobas c501 and 2) an evaluation of precision for the HbA1c 501 system.

Materials and Methods:

The test with HemoCue HbA1c 501 was performed at three primary care sites: VC Laxen, VC Förslöv and Läkarhuset Roslunda AB. The test on the comparative method, Roche's Cobas c501, was performed at Ängelholm's hospital. Left over blood samples from the routine sampling procedure were used. These were analyzed with two replicates using HemoCue HbA1c 501 and one replicate using Roche Cobas c501. Two different cartridge batches were used.

The users were provided with quick reference guide and operating manual before start of the study and were asked to answer a questionnaire after finished the study. None of the users had experience of another point of

care HbA1c system.

Three of the venous samples used in the method comparison were used in an additional evaluation of precision. The samples represented three different HbA1c levels (low, middle and high) and were analyzed in 20 replicates with one of the cartridge batches.

Results:

Linear regression analysis between the results produced the regression line: $Y = 1,04x - 1,55$, $R^2 = 0,981$. $N = 109$ (Figure 1a).

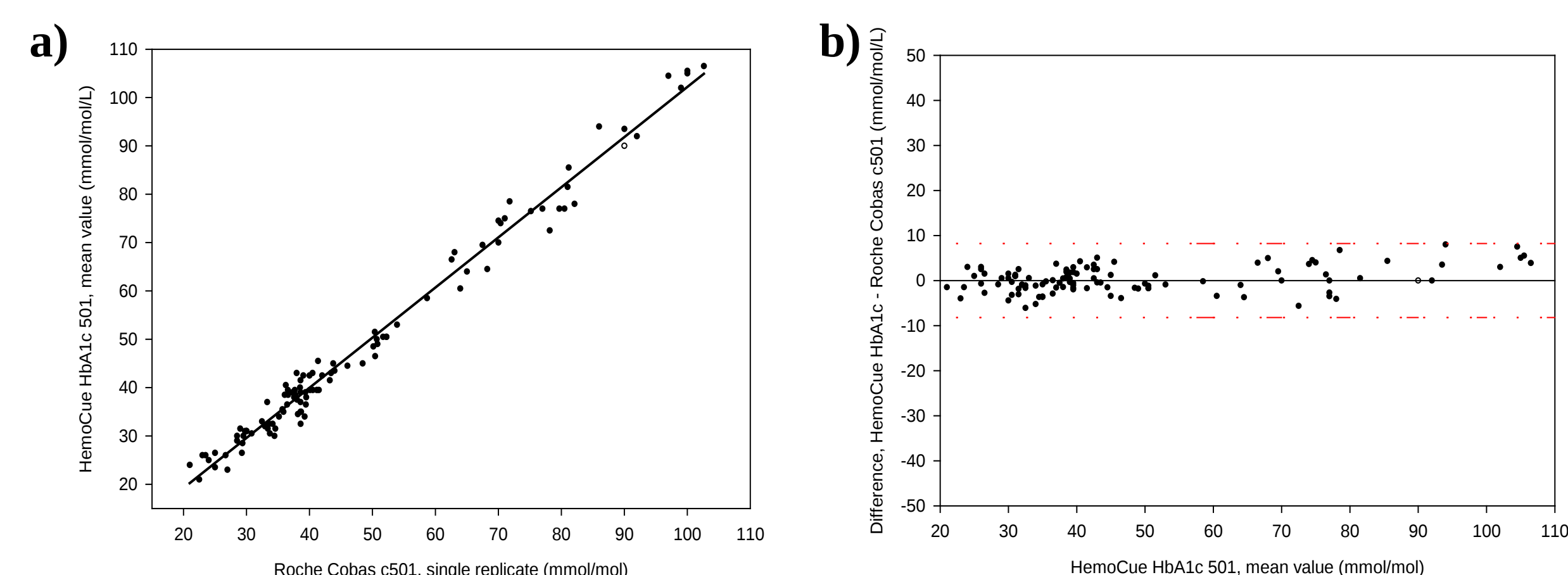


Figure 1a: Scatter plot for HbA1c 501 (y) versus Roche Cobas c501 (x), mmol/mol. $Y = 1,04x - 1,55$, $R^2 = 0,981$. $N = 109$. **Figure 1b:** HemoCue HbA1c 501 system fulfils the criteria for accuracy according to NGSP when compared to Roche Cobas c501. Blue line represents $\pm 0,75$ HbA1c-% ($\pm 8,2$ mmol/mol).

According to NGSP (National Glycohemoglobin Standardization Program): 95% of the results must be within $\pm 0,75$ % HbA1c ($\pm 8,2$ mmol/mol) compared to the reference method. HemoCue HbA1c 501 system fulfils the criteria for accuracy according to NGSP (99,1 of the results within $\pm 8,2$ mmol/mol) when compared to Roche Cobas c501 (Figure 1b).

SD and CV% for the duplicate samples run on HemoCue HbA1c 501 in the method comparison study were calculated to 1,54 and 3,2, respectively. Calculated SD and CV% in the additional precision study is

Table 1: Precision, SD and CV for HemoCue HbA1c 501.

Group:	Mean, mmol/mol	SD mmol/mol	CV %
Low	29,4	1,0	3,4
Middle	38,9	1,4	3,6
High	108,0	3,5	3,2

presented in Table 1.

All of the users except one thought that the usability was good when having learned how to remove the cartridge from the cartridge compartment. The self instructive display together with the small size was the best advantage of the system and all of the users thought the quick guide was good. One user thought the analyzer was loud in periods, but appreciated that it was totally quiet in standby mode.

Discussion:

There are various ways of setting goals for analytical quality. However, there are no generally recognized analytical quality goals for HbA1c determinations. In this evaluation we have used definition of accuracy according to NGSP.

We have compared the HemoCue HbA1c 501 system to the Roche Cobas c501. There is a very good agreement between these systems in a broad range of glycemia. The acceptance criteria for accuracy according to NGSP are fulfilled.

According to intended users, the usability of the new HemoCue HbA1c 501 system is good. The system is small, has a self instructive display and together with the quick reference guide it is easy for the intended users to perform a patient test.

References:

- 1) 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.
- 2) The United Kingdom Prospective Diabetes Study (UKPDS)