**Evaluation of the HemoCue® HbA1c 501 system in primary care settings**

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**Introduction**

The routine measurement of hemoglobin A1c (HbA1c) has become an essential component of the standard of care for patients with diabetes. By providing results rapidly following blood collection with point-of-care (POC) devices, diabetes care providers can give patients immediate feedback and make more timely decisions regarding optimal treatment. As newer POC HbA1c devices enter the market, evaluation of performance, as well as comparison with reference standards are needed. According to the latest National Glycohemoglobin Standardization Program (NGSP) for manufacturer certification, 37 of 40 results (or 92.5%) should be within +/- 6%. For optimal clinical monitoring, an imprecision of 2% CV would be desirable. This criteria is however very strict and currently an imprecision of 3% CV is considered a more realistic goal. The aim of this study was to evaluate the performance of the new HemoCue® HbA1c 501 system during regular use in primary care settings.

**Methods**

Venous and capillary samples were collected from 114 subjects at two primary health care centers in Sweden over a period of one month. The study included non-diabetic, pre-diabetic, as well as already diagnosed patients with diabetes type I and type II. On each subject, the users performed a finger stick and collected capillary blood for immediate testing with the HemoCue system. In addition, a venous sample in a K2EDTA tube was obtained from the same patient and analyzed on the same day with the HemoCue system. The remaining venous sample was sent to a reference lab for testing with the Tosoh G8 HPLC method within 4 days of collection. After the study completion, all users were given a questionnaire regarding how they experienced the use of the HemoCue system in terms of general aspects of the system, understanding of the instructions for use and overall impression.

**Results**

HbA1c levels measured with the HemoCue system aligned with measurements obtained using the Tosoh GB reference method, with correlation coefficients of 0.992. All measurements totally as well as venous and capillary samples separately, met the tighter NGSP criteria and the total CV% was 1.9. The responses to the questionnaire showed that the users found the HemoCue system easy to use and that the displayed results as well as the instructions for use were easy to interpret and follow.

**Conclusion**

The result from this field study verifies that the HemoCue® HbA1c 501 system is accurate and easy to use in the hands of the intended user in a primary care setting. This is based on the fact that >96% of results fall within 6% bias and a total CV of <2%, thereby fulfilling the latest NGSP requirements.