

# InnovaStar Analyzer, HbA1c A



## Summary of an evaluation under the direction of SKUP Report SKUP/2014/101

### Background

Med-Kjemi, Norway turned to SKUP for an evaluation of InnovaStar HbA1c. The evaluation was performed in the Department of Clinical Biochemistry, Nordsjællands Hospital, Denmark and in two primary health care centres, December 2013 to January 2014.

### The aim of the evaluation

The aim of the evaluation was to examine the repeatability and accuracy of InnovaStar HbA1c achieved with capillary and venous samples in a hospital laboratory, and to examine the repeatability and accuracy achieved with capillary samples by the intended end-users in two primary health care centres. The aim was also to evaluate the use of the control materials TruLab HbA1c liquid from DiaSys and to evaluate the user-friendliness of InnovaStar HbA1c.

### Materials and methods

102 venous whole blood EDTA samples and 40 capillary samples were examined in a hospital laboratory. Capillary samples from 88 patients were analysed in the primary health care centres. Repeatability and bias were calculated from duplicate results for three or two levels of HbA1c. Three lots of reagent cartridges were used. Quality goals for repeatability was  $\leq 3\%$  CV and for accuracy  $\geq 95\%$  of results deviating  $\leq \pm 10\%$  from the results of the comparison method (based on calculations in IFCC units (mmol/mol)).

### Results

At the hospital laboratory the repeatability was 1,9% for capillary samples and 1,6% for venous samples. In one primary health care centre the CV was 0,9% and 1,2% in two concentration levels, and in the other the CV was 1,8% and 3,2% at HbA1c mean 36,9 and 53,6 mmol/mol, respectively. In one primary health care centre the bias was +3,6 and -0,5%, while the other centre and the hospital laboratory had positive bias between +3,3 and +7,5%. In the hospital laboratory 68% of the capillary and 84% of the venous results were within the limits  $\pm 10\%$  from the comparison method. For results  $> 37$  mmol/mol, 94% were within the limits. For the two primary health care centres, the percentages within the limits  $\pm 10\%$  were 88% and 67%, respectively. The percentage of technical errors was 0,6%. The reproducibility was less than 3% for the control material TruLab HbA1c liquid level 1 and 2 in hospital and one of the primary health care centres. The other centre had CV% 4,5 and 3,5 for level 1 and 2, respectively. The users were satisfied with the user manual. The operation facilities were assessed as satisfactory. All evaluators agreed that the instrument required laboratory experience. The time factors and the quality control possibilities related to the InnovaStar HbA1c instrument were assessed as satisfactory.

### Conclusion

The goal for repeatability ( $< 3\%$ ) was fulfilled with venous, capillary and control results in the hospital laboratory. In one primary health care centre the quality goal for repeatability was fulfilled. In the other centre the goal was also fulfilled for low results, but most likely not fulfilled for high results and with the control materials.

The quality goal for accuracy ( $\geq 95\%$  of results deviating  $\leq \pm 10\%$  from the results of the comparison method) was neither fulfilled by the hospital laboratory (84 and 68%), nor by the two primary health care centres (73 and 88%). For results  $> 37$  mmol/mol, 94% of the venous results had a deviation less than  $\pm 10\%$  in hospital. The internal quality control material from the manufacturer was assessed as satisfactory.

The percentage of technical errors fulfilled the goal  $\leq 2\%$ . The user-friendliness of the manual and the operation facilities was satisfactory. The InnovaStar HbA1c instrument requires users with laboratory experience.

### Comments from the manufacturer

A letter with comments from DiaSys Diagnostic Systems is attached to the report.