

Accu-Chek Mobile blood glucose system

Summary of an evaluation under the direction of SKUP Report SKUP/2013/99*

Background for the evaluation

Accu-Chek Mobile is a blood glucose monitoring system designed for glucose self-measurements performed by persons with diabetes. The meter and test cassettes are produced by Roche Diagnostics GmbH and are already launched in Scandinavia. The Accu-Chek Mobile system was evaluated by SKUP in 2009. Later Roche has modified the test chemistry to prevent maltose interference. The end-users were not involved in the present SKUP evaluation, and the user-friendliness was not assessed.

The aim of the evaluation

- assess the analytical quality under standardised and optimal conditions, achieved by a biomedical laboratory scientist in a hospital environment
- examine the variation between three lots of test cassettes

Materials and methods

Capillary samples from 81 persons with diabetes and 9 persons without diabetes were collected. The sampling was carried out at Haraldsplass Diaconal Hospital. For each person two measurements on Accu-Chek Mobile were carried out, and a capillary sample was directly prepared for the comparison method. Three lots of test cassettes were used. The quality goal for imprecision was a repeatability CV $\leq 5\%$. The quality goal for accuracy was set according to ISO 15197:2003. The quality goal states that 95% of the individual glucose results shall fall within $\pm 0,83$ mmol/L of the results of the comparison method at glucose concentrations $< 4,2$ mmol/L and within $\pm 20\%$ at glucose concentrations $\geq 4,2$ mmol/L.

Results

- For glucose level > 10 mmol/L the repeatability CV was 3,0%. For glucose levels < 7 mmol/L and 7—10 mmol/L the repeatability CV was 4,1% and 4,2%, respectively.
- No bias was present at the three levels of glucose concentration, and 98% of the results were within the accuracy limits.
- One lot of test cassettes showed slightly lower results than the comparison method ($-0,4$ mmol/L), and one lot showed slightly higher results ($+0,3$ mmol/L). The third lot showed results in agreement with the comparison method.
- The percentage of technical errors was 1,5%.

Conclusion

The quality goal for imprecision (CV $\leq 5\%$), was fulfilled for glucose level > 10 mmol/L. For glucose level ≤ 10 mmol/L the CV was approximately 4%, with the upper CI value $> 5\%$. No bias was found. Only small deviations from the comparison method were found with the three lots of test cassettes. The results fulfilled the quality goal for accuracy specified in ISO 15197:2003. The percentage of technical errors fulfilled the goal ($\leq 2\%$).

Comments from Roche

Roche gratefully accepted the report and had no additional comments.

The complete report is found at www.skup.nu.