

Accu-Chek Aviva SKUP/2013/98*

Background for the evaluation

Accu-Chek Aviva is a blood glucose monitoring system designed for blood testing performed by health care professionals as well as by persons with diabetes. The system is produced by Roche Diagnostics GmbH and is already launched in Scandinavia. The Accu-Chek Aviva system was evaluated by SKUP in 2005. Later Roche has modified the test strip chemistry to prevent maltose interference. Roche Scandinavia ordered this new evaluation to get documentation required in the Swedish tender system. Because of the earlier evaluation, there was no need to involve the end-users or to evaluate the user-friendliness in the present SKUP evaluation.

The aim of the evaluation

The aim of the evaluation of Accu-Chek Aviva was to

- assess the analytical quality under standardised and optimal conditions, achieved by a biomedical laboratory scientist in an outpatient clinic and in two hospital wards
- examine the variation between three lots of test strips

Materials and methods

Capillary samples from 81 persons with diabetes and 9 persons without diabetes were collected. The sampling was carried out at Haralds plass Diaconal Hospital. For each person two measurements on Accu-Chek Aviva were carried out, and a capillary sample was directly prepared for measurement with a selected comparison method. Three test strip lots were used.

Results

- For glucose level <7 mmol/L the repeatability CV was 2,8%, and the recommended quality goal (CV $\leq 5\%$) was fulfilled. For glucose level 7–10 mmol/L and glucose level >10 mmol/L the repeatability CV was 4,2% and 4,5%, respectively. The upper CI value is $>5\%$, and the two data sets are inconclusive on fulfilling the quality goal. Most likely the quality goal is fulfilled.
- The glucose measurements on Accu-Chek Aviva showed systematic lower glucose results than the comparison method. The bias was between $-0,2$ and $-0,7$ mmol/L. The deviation was small, but statistically significant. All results except one were within the accuracy quality limits. The quality goal for accuracy specified in ISO 15197:2003 was fulfilled.
- The three lots of Accu-Chek Aviva test strips showed results in agreement.
- The percentage of technical errors was 1,4%.

Conclusion

The repeatability CV was between 2,8 and 4,5%. The recommended quality goal (CV $\leq 5\%$) was fulfilled for glucose level <7 mmol/L. For glucose level >7 mmol/L the quality goal is most likely fulfilled. The glucose measurements on Accu-Chek Aviva showed systematic lower glucose results than the comparison method. The deviation was between $-0,2$ and $-0,7$ mmol/L. The results fulfilled the quality goal for accuracy specified in ISO 15197:2003. The three lots of Accu-Chek Aviva test strips showed agreeing results. The percentage of technical errors fulfilled the goal ($\leq 2\%$).

Comments from Roche

None.