

Accu-Chek Aviva Glucose

Summary of an evaluation under the direction of SKUP Report SKUP/2005/44



Background

Accu-Chek Aviva is a meter designed for glucose self-measurements by diabetic patients. The meter is produced by Roche and is supplied in Scandinavia by Roche Diagnostics. Accu-Chek Aviva was launched onto the Norwegian market in July 2005.

In order to give reimbursement for the test strips, The National Social Insurance Office (*Rikstrygdeverket*) in Norway instructs the companies to carry out an evaluation that includes a user-evaluation among diabetic patients. The evaluation of Accu-Chek Aviva is done under the direction of SKUP during the spring of 2005.

The aim of the evaluation

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

- reflect the analytical quality under standardised and optimal conditions (performed by two biomedical laboratory scientists)
- reflect the analytical quality by the users (79 diabetics)
- compare the analytical quality among diabetics with and without training
- compare the analytical quality among diabetics before and after three weeks of practise
- check the variations between three lots of test strips
- examine if hematocrit interferes with the measurements
- evaluate Accu-Chek Aviva regarding user-friendliness
- evaluate the Accu-Chek Aviva user-manual

Materials and methods

79 diabetic patients took part in the evaluation. 40 participants had two consultations (the “training group”) and 39 participants had one consultation (the “postgroup”). At the first consultation the “training group” was given a standardised instruction about the Accu-Chek Aviva before they did a finger prick and performed two measurements on the meter. The biomedical laboratory scientist also took capillary samples of the diabetic patients and measured twice at Accu-Chek Aviva. In addition, two capillary samples were taken to a designated comparison method. The “postgroup” received Accu-Chek Aviva by post and no training was given. Both groups of diabetics carried out a practice period of approximately three weeks at home, before they were called for a final consultation. The blood glucose sampling and measurement procedures at the first consultation were repeated, and in addition a sample for hematocrit was taken. Three different lots of test strips were used in the evaluation. All the participants finally answered questionnaires about the user-friendliness and the user-manual of Accu-Chek Aviva.

Results

- Accu-Chek Aviva shows acceptable precision. The CV is < 5 % under standardised and optimal measuring conditions and approximately 5 % when the measurements are performed by diabetic patients.
- The agreement with a designated comparison method is good. Quality goals set in ISO 15197 are achieved under standardised and optimal measuring conditions. When handled by the diabetic patients, Accu-Chek Aviva also shows good results. 97 % of these results

are within the “adjusted ISO-goal” and 96 % are also within the quality goals set in ISO 15197.

- Two of the three lots of test strips that were used showed significantly higher values than the comparison method. The measured differences have no clinical importance.
- Glucose measurements on Accu-Chek Aviva do not seem to be affected by hematocrit values between 28 – 49 %. Hematocrit outside this range has not been tested.
- The diabetic patients summarise the Accu-Chek Aviva device as easy to use. As a whole they were pleased with the device. The patients that had used the user manual were satisfied with the manual.

Conclusion

Glucose measurements on Accu-Chek Aviva have acceptable precision. The results obtained under standardised and optimal measuring conditions are within the quality goals set in the ISO-guide 15197. The measurements performed by the diabetic patients are also within the ISO-goal. The glucose results in this evaluation are not affected by hematocrit. The users say that the Accu-Chek Aviva device is easy to use and they are quite satisfied with the device.

Comments from Roche Diagnostics

There is no additional information from producer attached to the report.

The complete report is found at www.skup.nu