

Accu-Chek Compact Plus Glucose

Summary of an evaluation under the direction of SKUP Report SKUP/2005/43



Background

Accu-Chek Compact Plus is a meter designed for glucose self-measurements by diabetics. The meter is produced by Roche and is supplied in Scandinavia by Roche Diagnostics. Accu-Chek Compact Plus was launched onto the Norwegian market in May 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 diabetics. The evaluation of Accu-Chek Compact Plus 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 Compact Plus is to

- reflect the analytical quality under standardised and optimal conditions (performed by biomedical laboratory scientists)
- reflect the analytical quality by the users (80 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 variation between three lots of test strips
- examine if hematocrit interferes with the measurements
- evaluate Accu-Chek Compact Plus regarding user-friendliness
- evaluate the Accu-Chek Compact Plus user-manual

Materials and methods

80 diabetics took part in the evaluation. 40 participants had two consultations (the “training group”) and the rest had one consultation (the “post group”). At the first consultation the diabetics in the training group were given a standardised instruction about the Accu-Chek Compact Plus before they did a finger prick and performed two measurements on the meter. The biomedical laboratory scientists also took capillary samples of the diabetics and measured twice at Accu-Chek Compact Plus. In addition, two capillary samples were taken to a designated comparison method. The post group received the Accu-Chek Compact Plus 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 Compact Plus.

Results

- Accu-Chek Compact Plus shows acceptable precision. The CV is approximately 3 % under standardised and optimal measuring conditions and between 3 and 6 % when the measurements are performed by diabetics.
- The agreement with a designated comparison method is good. Quality goals set in ISO 15197 are achieved under standardised and optimal measuring conditions, and at the final consultation even the quality goals set by ADA are achieved. When handled by the diabetics, Accu-Chek Compact Plus also shows accurate results. 100 % of these results

are within the “adjusted ISO-goal” and 99 % are also within the quality goals set in ISO 15197.

- One of the three lots of test strips that were used showed significantly lower values than the comparison method. In spite of this deviation, the results attain the quality goal.
- Glucose measurements at Accu-Chek Compact Plus seem to be affected by the hematocrit values of the samples in higher degree than described in the package insert. Glucose values are over-estimated when the hematocrit is below 35 %. With hematocrit values over approximately 45 % the glucose values are under-estimated.
- The diabetics summarise the Accu-Chek Compact Plus device as easy to use. As a whole they were pleased with the device. The diabetics that had used the user manual were satisfied with the manual.

Conclusion

Glucose measurements on Accu-Chek Compact Plus 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 diabetics are also within the ISO-goal. One of the three lots of test strips that were used showed significantly lower values than the comparison method, but the results are still within the ISO-goal. The glucose results in this evaluation are affected by hematocrit in a higher degree than described in the package insert. In spite of the hematocrit effect, the glucose results still fulfil the quality goal set by ISO. The users find the Accu-Chek Compact Plus device 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