

Accu-Chek Sensor Glucose

Summary of an evaluation under the direction of SKUP Report SKUP/2006/48



Background

The Accu-Chek Sensor meter and the Accu-Chek Sensor Comfort Glucose test strips are designed for glucose self-measurements by diabetics. The meter and the test strips are produced by Roche and are supplied in Scandinavia by Roche Diagnostics. The system was launched onto the Norwegian market in 1998.

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 Sensor/Accu-Chek Sensor Comfort Glucose is done under the direction of SKUP from October to December 2005. Further on in the report Accu-Chek Sensor/Accu-Chek Sensor Comfort Glucose will be referred to as Accu-Chek Sensor.

The aim of the evaluation

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

- reflect the analytical quality under standardised and optimal conditions (performed by a biomedical laboratory scientist)
- reflect the analytical quality by the users (77 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 Sensor regarding user-friendliness
- evaluate the Accu-Chek Sensor user-manual

Materials and methods

77 diabetics took part in the evaluation. 39 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 Sensor before they did a finger prick and performed two measurements at the meter. The biomedical laboratory scientist also took capillary samples of the diabetics and measured twice at Accu-Chek Sensor. In addition, two capillary samples were taken to a designated comparison method. The “post group” received the Accu-Chek Sensor 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 Sensor.

Results

- Accu-Chek Sensor shows acceptable precision. The CV is approximately 3 % under standardised and optimal measuring conditions and between 2 and 6 % when the measurements are performed by diabetics.

- The trueness of Accu-Chek Sensor is good. Accu-Chek Sensor gives glucose values from 0,1 – 0,3 mmol/L higher than the comparison method. This bias has no importance and the results still fulfil the quality goal set by ISO.
- 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 diabetics, Accu-Chek Sensor also shows accurate results. These results are within the “adjusted ISO-goal” and 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 bias is small, and the results still attain the quality goal.
- Glucose measurements at Accu-Chek Sensor do not seem to be affected by hematocrit values between 35 – 50 %. Hematocrit outside this range has not been tested.
- The diabetics summarise the Accu-Chek Sensor device as easy to use. Most of them were pleased with the device. The diabetics that had used the user manual were satisfied with the manual.

Conclusion

Glucose measurements at Accu-Chek Sensor 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-goals. Two of the three lots of test strips that were used showed significantly higher values than the comparison method. The bias is small, and the results still attain the quality goal. The glucose results do not seem to be affected by hematocrit. The users find the Accu-Chek Sensor 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