

Accu-Chek Mobile blood glucose system



Summary of an evaluation under the direction of SKUP Report SKUP/2009/74

Background

Accu-Chek Mobile blood glucose meter and Accu-Chek Mobile test cassettes are designed for glucose self-measurements performed by diabetes patients. The meter and test strips are produced by Roche Diagnostics GmbH and supplied in Scandinavia by Roche. The system has not yet been launched onto the Norwegian market. In order to give reimbursement for the test strips in Norway, the Norwegian Labour and Welfare Organisation (NAV) requires from the companies to carry out an evaluation that includes a user-evaluation among diabetes patients. The SKUP-evaluation of Accu-Chek Mobile was carried out under the direction of SKUP from Mars to September 2009.

The aim of the evaluation

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

- reflect the analytical quality under standardised and optimal conditions, performed by a biomedical laboratory scientist in a hospital environment
- reflect the analytical quality by the intended users
- compare the analytical quality among trained and un-trained diabetes patients
- examine the variation between three lots of test cassettes
- examine if hematocrit interferes with the measurements
- evaluate Accu-Chek Mobile regarding user-friendliness
- evaluate the Accu-Chek Mobile user guide

Materials and methods

88 diabetes patients took part in the evaluation. 44 participants had two consultations and the rest had one consultation. The diabetes patients in the “training group” were given a standardised instruction about Accu-Chek Mobile before they did a finger prick and performed two measurements on the meter. The biomedical laboratory scientist also collected capillary samples from the diabetes patients and measured twice on Accu-Chek Mobile. In addition, two capillary samples were taken for measurements with a designated comparison method. The diabetes patients in the “mail group” received Accu-Chek Mobile by mail and no training was given. Both groups of diabetes patients used the equipment for approximately three weeks at home, before they attended 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 cassettes were used in the evaluation. All the participants answered questionnaires about the user-friendliness and the user guide of Accu-Chek Mobile.

Results

- The overall precision of Accu-Chek Mobile was good. The repeatability CV obtained under standardised and optimal conditions was <3%. When the measurements were performed by the diabetes patients an improvement in repeatability was seen at the second consultation. This led to a repeatability CV at approximately 4%.
- For glucose concentrations <10 mmol/L, the results on Accu-Chek Mobile were systematic higher than the results from the comparison method. The mean deviation from the comparison method at this concentration level was approximately +0,3 mmol/L. For glucose concentrations >10 mmol/L Accu-Chek Mobile gave results in agreement with the comparison method.
- The accuracy of Accu-Chek Mobile was good. The results fulfilled the quality goal proposed in ISO 15197. More than 95% of the results achieved under standardised and optimal conditions were within the limits described in ISO 15197. The “adjusted ISO-goal” was met

by the measurements of the diabetes patients, and >95% of the results achieved by the diabetes patients also fulfilled the ISO-goal.

- Two of the three lots of test cassettes used in the evaluation gave significantly higher values than the comparison method. The mean deviation from the comparison method was approximately +0,4 mmol/L .
- Glucose measurements on Accu-Chek Mobile seemed to be slightly affected by hematocrit in this study. Hematocrit outside the range 27 – 49% has not been tested.
- Most of the diabetes patients thought that the Accu-Chek Mobile device was easy to operate. Some of the participants had problems related to opening the tip cover. Most of the diabetes patients that had used the user guide were satisfied with the guide.

Conclusion

The precision of Accu-Chek Mobile was good. The repeatability CV was between 2,5 and 5%. The accuracy of Accu-Chek Mobile was good, and the results fulfilled the quality goal based on ISO 15197. Glucose measurements on Accu-Chek Mobile seemed to be slightly affected by hematocrit in this study. Most of the users found the Accu-Chek Mobile device easy to use.

Comments from Roche Diagnostics

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

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