

# Accu-Chek Performa blood glucose system

## Summary of an evaluation under the direction of SKUP Report SKUP/2011/93\*

### Background for the evaluation

Accu-Chek Performa 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 Performa test strip is almost identical with the test strip evaluated in SKUP/2005/44. Roche in Sweden ordered this new evaluation as part of necessary documentation required in a Swedish tender system. There was no need to involve the end users in the present SKUP evaluation.

### The aim of the evaluation

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

- assess the analytical quality under standardised and optimal conditions, performed by a biomedical laboratory scientist in a hospital environment
- examine the variation between three lots of test strips
- evaluate the Accu-Chek Performa owner's booklet and the user-friendliness of Accu-Chek Performa (by one biomedical laboratory scientist)

### Materials and methods

Capillary samples from 78 persons with diabetes and 12 persons without diabetes were collected. The sampling was carried out at Haraldsplass Diaconal Hospital. For each person two measurements on Accu-Chek Performa were carried out, and a capillary sample was directly prepared for measurement with a selected comparison method. Three lots of test strips were used. The user-friendliness of Accu-Chek Performa was assessed by means of a questionnaire.

### Results

- The precision of Accu-Chek Performa was good. The repeatability CV was between 2,9 and 4,1%. The suggested quality goal for precision was obtained
- Accu-Chek Performa showed glucose results in agreement with the comparison method for glucose concentrations <10 mmol/L. For glucose concentrations >10 mmol/L Accu-Chek Performa had a deviation from the comparison method of -0,5 mmol/L
- The assessment of the accuracy showed that Accu-Chek Performa glucose results were within the accepted quality limits according to ISO 15197
- One of the three lots gave glucose results in agreement with the comparison method. For the two other lots the deviation was -0,28 mmol/L and -0,41 mmol/L, respectively
- The user-friendliness and the owner's booklet were assessed as satisfactory by the biomedical laboratory scientist
- Fraction of technical errors was <2%

### Conclusion

The precision of Accu-Chek Performa was good. For glucose concentrations above approximately 10 mmol/L, the results on Accu-Chek Performa were systematically lower than the results from the selected comparison method. The bias was -0,5 mmol/L. The results fulfilled the quality goal proposed in ISO 15197. The user-friendliness and the owner's booklet were assessed as satisfactory. The fraction of technical errors was <2%, and the quality goal was fulfilled.

### Comments from Roche

A letter with comments from Roche is attached to the report.