FreeStyle *Lite* blood glucose system

Summary of an evaluation under the direction of SKUP
Report SKUP/2010/89*

Background
FreeStyle Lite blood glucose meter and FreeStyle Lite test strips are designed for glucose self-measurements performed by diabetes patients and measurements performed by health care professionals. The meter and the test strips are produced by Abbott Diabetes Care Inc. and supplied in Scandinavia by Abbott. FreeStyle Lite was evaluated by SKUP in 2007 and was launched onto the Norwegian market in 2007. The need of a verification of the evaluation from 2007 is due to change of the coenzyme in the test strips from pyrroloquinolone quinone (PQQ) to flavin-adenine dinucleotide (FAD). In addition Abbott wanted the FreeStyle Lite test strip to be evaluated with focus on the analytical quality according to a goal suggested by NOKLUS in 2008 for glucose instruments used in primary health care centres and nursing homes. The quality goal allows a total error of 10%. The new evaluation of FreeStyle Lite was first carried out in a hospital laboratory environment during February and March 2010. The accuracy results were discussed with Abbott in a meeting in May 2010. Following the evaluation, Abbott had centred the product factory calibration after having more clinical data available. Abbott therefore asked SKUP to repeat the evaluation of FreeStyle Lite. The evaluation was repeated during October and November 2010.

The aim of this evaluation
The aim of this evaluation of FreeStyle Lite was to

- assess the analytical quality under standardised and optimal conditions, performed by a biomedical laboratory scientist in a hospital environment
- discuss achieved total measurement error according to a quality goal of 10%, suggested by NOKLUS as a quality goal for glucose devices used in primary health care and nursing homes
- examine the variation between three lots of test strips

Materials and methods
Capillary samples from 80 persons with diabetes and 10 healthy individuals were collected. The sampling of the diabetes patients was carried out in a medical outpatient clinic at Haraldsplass Diaconal Hospital. For each person two measurements on FreeStyle Lite were carried out, and a capillary sample was directly prepared for measurement with a designated comparison method. Three different lots of test strips were used.

Results
- The precision of FreeStyle Lite was good. The repeatability CV was <3%. The suggested quality goal for precision was obtained.
- FreeStyle Lite showed glucose results in agreement with the comparison method for glucose concentrations <7 mmol/L. Statistically, FreeStyle Lite showed significantly lower glucose results than the comparison method for glucose concentrations >7 mmol/L. For glucose concentrations between 7 and 10 mmol/L the deviation was small but

statistically significant. The deviation was approximately -1,0 mmol/L for glucose concentrations above 10 mmol/L.

- The assessment of the accuracy confirmed that FreeStyle Lite glucose results were in agreement with the comparison method for glucose concentrations <7 mmol/L. For glucose concentrations above approximately 7 mmol/L most of the results on FreeStyle Lite were lower than the results from the comparison method. The quality goal proposed in ISO 15197 was fulfilled.
- The total error of FreeStyle Lite was between 4,6 and 10,4%. Assessed as a whole, the total error was below 10%. The suggested quality goal for use in Norwegian primary health care centres and nursing homes was obtained.
- Glucose results on FreeStyle Lite with two of the three lots of test strips used in this evaluation were systematic lower than the results achieved with the comparison method. The deviation was -0,35 mmol/L for lot 1071713 and -0,65 mmol/L for lot 1071910. Lot 1071901 gave glucose results in agreement with the comparison method.

Conclusion

The precision of Free Style Lite was good, with a repeatability CV <3%. For glucose concentrations above approximately 7 mmol/L, the results on FreeStyle Lite were systematically lower than the results from the designated comparison method. The bias was from -0,2 mmol/L to -1,0 mmol/L. The results fulfilled the quality goal proposed in ISO 15197. The suggested quality goal for use in Norwegian primary health care centres and nursing homes was obtained.

Comments from Abbott

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

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