mylife PURA

Summary of an evaluation under the direction of SKUP
Report SKUP/2010/81*

Background
Mylife Pura blood glucose meter and test strips are designed for glucose self-measurements performed by diabetes patients. The meter and test strips are produced by Bionime Corporation and supplied in the Nordic countries by Ypsomed AG. The mylife Pura system has not been launched onto the Scandinavian market yet. Mylife Pura is a new version of the previous system from Bionime; Bionime Rightest. SKUP organised a user evaluation of Rightest among diabetes patients in 2007. The results were good, but revealed a test strip that was calibrated to give whole blood glucose equivalent values. The required evaluation of mylife Pura was carried out in a hospital laboratory environment during February and March 2010.

The aim of the evaluation
The aim of the evaluation of mylife Pura was to

- assess the analytical quality under standardised and optimal conditions, performed by a biomedical laboratory scientist in a hospital environment
- assess the accuracy according to the quality goals set in ISO 15197
- discuss achieved total measurement error according to a quality goal of 10%, suggested by NOKLUS for glucose device used in primary care and nursing homes in Norway
- examine the variation between three lots of test strip

Materials and methods
Capillary samples from 82 persons with diabetes and 8 healthy individuals were collected. The sampling of the diabetes patients was carried out in a medical outpatient clinic at Haraldsplass Diaconal Hospital in Bergen. For each person two measurements on mylife Pura were performed, 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 mylife Pura was good. The repeatability CV was just above 2%. The suggested quality goal for precision was obtained.
- The glucose results on mylife Pura were systematic lower than the results from the designated comparison method. The mean deviation was -0,6 mmol/l (11%) for glucose concentrations below 7 mmol/L, -0,9 mmol/L (11%) for glucose concentrations between 7 and 10 mmol/L and -1,4 mmol/L (10%) for glucose concentrations above 10 mmol/L.
- The assessment of the accuracy confirmed the systematic deviation of the results. All results on mylife Pura were lower than the results from the comparison method. The results still fulfilled the quality goal proposed in ISO 15197.
- The total error of mylife Pura was between 13 and 15%. The suggested quality goal for use in Norwegian primary care centres and nursing homes was not obtained.

- The three lots of mylife Pura test strips gave corresponding results and lower than the results from the comparison method. The mean deviation was approximately -1,0 mmol/L for all three lots.

Conclusion

The precision of mylife Pura was good, with a repeatability CV just above 2%. The glucose results on mylife Pura were approximately 11% lower than the results from the comparison method. The suggested quality goal for use in Norwegian primary care centres and nursing homes with a total error <10% was not obtained. The results fulfilled the quality goal proposed in ISO 15197.

Comments from Ypsomed AG

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

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