Summary | Actiste for measurement of glucose

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Manufacturer: Brighter AB
Supplier: Brighter AB in Sweden

Summary of an evaluation provided by SKUP

Conclusion

- **The quality goal for repeatability was not fulfilled**
- **The quality goal for accuracy was not fulfilled**
- **The quality goal for user-friendliness was not fulfilled**

Background
The Actiste system is a combined in vitro diagnostic device for capillary blood sampling and quantitative measurement of glucose, and medical device for insulin injections. The product is intended for monitoring of disease in persons with insulin-dependent diabetes. The sample material is fresh capillary whole blood. The system is produced by Brighter AB and was launched into the Scandinavian market May 2020. The SKUP evaluation was carried out February 2020 to February 2021 at the request of Brighter AB in Sweden.

The aim of the evaluation
The aim of the evaluation was to assess the analytical quality and user-friendliness of glucose measurements with Actiste, both when used under optimal conditions by experienced laboratory personnel and under real-life conditions by intended users (persons with diabetes). The medical device for insulin injections was not evaluated.

Materials and methods
The study design is based on the model of the Norwegian Health Economics Administration (HELFO) for test strip reimbursement in Norway. A total of 97 persons with diabetes signed up for the evaluation and 86 of them completed. All participants received the device and instructions by mail and no training was given. They used the device for approximately two weeks at home, before they attended an evaluation meeting at the central hospital in Växjö, Sweden or at Noklus in Bergen, Norway. Fresh capillary whole blood samples from each participant were analysed on Actiste under optimal conditions as well as by the participants. Three lots of test strips were used. Capillary samples from the same individuals were analysed on a comparison method (a glucose hexokinase method for measurement of glucose in plasma, implemented on Roche Cobas 8000 c 701) in the laboratory for clinical chemistry and transfusion medicine at the central hospital in Växjö, Sweden. The trueness of the comparison method was demonstrated with the standard reference material (SRM) 965b from the National Institute of Standards & Technology (NIST). Haematocrit was analysed in venous samples. The analytical results and user-friendliness were assessed according to pre-set quality goals. The quality goal for precision was a repeatability (CV) ≤5,0 %. The quality goal for accuracy follows to the International Organization for Standardization (ISO) 15197:2013 which states that at least 95 % of the individual glucose results shall be <±0,83 mmol/L of the average measured values of the reference measurement procedure at glucose concentration <5,55 mmol/L or <±15 % at glucose concentration ≥5,55 mmol/L. The user-friendliness was assessed using a questionnaire with three given ratings; satisfactory, intermediate and unsatisfactory, and with the quality goal of a total rating of “satisfactory”.

Results
The CV achieved under optimal conditions was between 3,6 and 5,8 % depending on the glucose concentration. The intended users achieved a CV between 5,3 and 7,2 %. The bias between Actiste and the comparison method was between 0,6 and 0,9 mmol/L under optimal conditions and between 0,8 and 1,5 mmol/L for the intended users. Under optimal conditions 81 – 86 % of the results, depending on lot number, were within the allowable deviation limits for accuracy and when handled by intended users, 58 % of the results were within the limits. Glucose measurements on Actiste were not affected by haematocrit in the tested range 36 – 54 %. The user-friendliness of the operation facilities was rated as unsatisfactory and the manual as intermediate, while the other topics were rated as satisfactory.

Conclusion
The quality goal for repeatability was not fulfilled neither under optimal conditions nor by intended users. The quality goal for accuracy was not fulfilled neither under optimal conditions nor by intended users. The quality goal for user-friendliness was not fulfilled.

Comments from Brighter AB
A letter with comments from Brighter AB is attached to the report.

This summary is also published in Danish, Norwegian and Swedish at www.skup.org.