Summary

Summary of an evaluation provided by SKUP
Accu-Chek Guide for measurement of glucose
Manufacturer: Roche Diabetes Care GmbH
Supplier: Roche Diagnostics A/S in Denmark/Roche Diabetes Care Norge AS in Norway/Roche Diagnostics Scandinavia AB in Sweden

Conclusion
The quality goal for repeatability was fulfilled under optimal conditions as well as by intended users. The quality goal for accuracy was fulfilled both under optimal conditions and when measurements were performed by intended users. The quality goal for user-friendliness was fulfilled.

Background
Accu-Chek Guide is an in vitro device for the quantitative measurement of glucose and is designed for monitoring. The product is intended for persons with diabetes and health care professionals. The sample material is whole blood, preferably capillary blood. The system is produced by Roche Diabetes Care GmbH and was launched into the Scandinavian market in October 2016. The SKUP evaluation was carried out in October 2016 at the request of Roche Diabetes Care Norge AS.

The aim of the evaluation
The aim of the evaluation was to assess the analytical quality and user-friendliness of Accu-Chek Guide, both when used under optimal conditions by experienced laboratory personnel and under real-life conditions by intended users (persons with diabetes). The analytical results were assessed according to pre-set quality goals.

Materials and methods
A total of 90 persons with diabetes participated in the evaluation. All the 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 SKUP. Fresh whole blood capillary samples from each participant were analysed on Accu-Chek Guide 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 6000, Roche Diabetes Care). The quality goal for imprecision was a repeatability (CV) ≤5,0 %. The quality goal for accuracy was set according to the International Organization for Standardization (ISO) ISO 15197:2013. This quality goal states that at least 95 % of the individual glucose results shall be within <±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 quality goal for the user-friendliness was a total rating of "satisfactory".

Results
The CV achieved under optimal conditions was between 1,5 and 2,6 %. The intended users achieved a CV between 1,8 and 3,9 %. There was a negative bias of (–0,1) — (–0,8) mmol/L between Accu-Chek Guide and the comparison method. Both under optimal conditions and when handled by the intended users, 100 % of the results were within the quality goal for accuracy. Glucose measurements on Accu-Chek Guide were not affected by haematocrit in this evaluation (tested haematocrit range 31—50 %). The user-friendliness was rated as satisfactory. The fraction of tests wasted caused by technical errors was 0,8 %.

Comments from Roche Diabetes Care Norge AS
Roche Diabetes Care Norge AS has accepted the report without further comments.