Summary | Accu-Chek Instant 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

Summary of an evaluation provided by SKUP

Conclusion

- **The quality goal for repeatability was fulfilled under optimal conditions, but not fulfilled by intended users due to the higher imprecision for glucose concentration <7 mmol/L.**
- **The quality goal for accuracy was fulfilled both under optimal conditions and by intended users.**
- **The quality goal for user-friendliness was fulfilled.**

Background
The Accu-Chek Instant system is an in vitro diagnostic device for quantitative measurement of glucose. The product is intended for professional use and self-testing. The sample material is fresh capillary whole blood. The system is produced by Roche Diabetes Care GmbH and was launched into the Scandinavian market in May 2018. The SKUP evaluation was carried out in May and June 2017 at the request of Roche Diagnostics Scandinavia AB.

The aim of the evaluation
The aim of the evaluation was to assess analytical quality and user-friendliness of Accu-Chek Instant, 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 signed up for the evaluation and 88 of them completed. 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 capillary whole blood samples from each participant were analysed on Accu-Chek Instant 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). The quality goal for precision 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 <±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 user-friendliness was a total rating of "satisfactory".

Results
The CV achieved under optimal conditions was between 1,6 and 2,9 % depending on the concentration level. The intended users achieved a CV between 2,1 and 5,7 %. The high imprecision at 5,7 % refers to results with glucose concentration <7 mmol/L. There was a bias between Accu-Chek Instant and the comparison method. The bias was between -0,08 and -0,65 mmol/L. Under optimal conditions, 100 % of the results were within the allowable deviation limits for accuracy and when handled by intended users, 99 % of the results were within the limits. Glucose measurements on Accu-Chek Instant were not affected by haematocrit (tested haematocrit range 29 - 50 %). The user-friendliness was rated as satisfactory. The fraction of tests wasted due to technical errors was 0,4 %.

Comments from Roche Diagnostics Scandinavia AB
Roche Diagnostics Scandinavia AB has accepted the report without further comments.

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