

Accu-Chek Aviva blood glucose system



Summary of an evaluation under the direction of SKUP Report SKUP/2014/105

Background

Roche Diagnostics Norge applied to SKUP for an evaluation of an updated version of the Accu-Chek Aviva meter and the Accu-Chek Aviva test strips with maltose independence chemistry.

The aim of the evaluation was to

- estimate the imprecision of Accu-Chek Aviva
- compare Accu-Chek Aviva results achieved under standardised and optimal conditions (hospital environment) and by the intended users with results from an established hospital laboratory method for glucose
- examine the variation between three lots of test strips
- examine if haematocrit interferes with the glucose measurements
- evaluate the user-friendliness of Accu-Chek Aviva and the user manual

Materials and methods

A total of 92 persons with diabetes signed up for the evaluation and 89 of them completed 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 the evaluation meeting. Three lots of test strips were used. The quality goal for imprecision was a repeatability CV $\leq 5\%$. The decision whether the achieved CV on three glucose concentration levels fulfils the quality goal or not is made on a 5% significance level. The quality goal for accuracy was set according to the International Organization for Standardization (ISO) 15197:2003¹ and ISO 15197:2013². These quality goals state that at least 95% of the individual glucose results shall fall within the accuracy limits.

¹ ISO 15197:2003: $\leq \pm 0,83$ mmol/L at glucose conc. $< 4,2$ mmol/L or $\leq \pm 20\%$ at glucose conc. $\geq 4,2$ mmol/L

² ISO 15197:2013: $\leq \pm 0,83$ mmol/L at glucose conc. $< 5,55$ mmol/L or $\leq \pm 15\%$ at glucose conc. $\geq 5,55$ mmol/L

Results

- The repeatability CV (with 90% CI) was between 2,4% (2,0 – 3,1) and 4,3% (3,7 – 5,4) as achieved by the biomedical laboratory scientists (BLSs) and between 4,3% (3,6 – 5,6) and 6,0% (5,0 – 7,4) as achieved by the diabetes patients.
- The glucose measurements on Accu-Chek Aviva showed systematic lower glucose results than the comparison method. The bias from the comparison method was between $-0,1$ and $-0,9$ mmol/L.
- All the results obtained by the BLSs were within the accuracy quality limits specified in ISO 15197:2003. All the results obtained by the BLSs with meter A/lot a and 98% of the results obtained with meter B/lot b and meter C/lot c were within the accuracy quality limits specified in ISO 15197:2013. All the results obtained by the diabetes patients were within the accuracy quality limits specified in ISO 15197:2003, and 95% of the results were within the accuracy quality limits specified in ISO 15197:2013.
- No difference between the results from the three lots of test strips was found.
- Glucose measurements on Accu-Chek Aviva were not affected by haematocrit (range 34 – 51%).
- The user-friendliness was rated as satisfactory.
- The percentage of technical errors was 0,9%.

Conclusion

The quality goal with a repeatability CV $\leq 5\%$ was fulfilled by the BLSs for all measurements except for measurements with a glucose level 7 – 10 mmol/L on meter B. For these measurements the repeatability most likely fulfilled the quality goal.

For measurements performed by the diabetes patients, the quality goal for repeatability was most likely fulfilled for glucose level <7 mmol/L and >10 mmol/L. For glucose level 7 – 10 mmol/L the quality goal for the repeatability CV was most likely not fulfilled.

The glucose measurements on Accu-Chek Aviva showed systematic lower glucose results than the comparison method. The results achieved by the BLSs and the results achieved by the diabetes patients fulfilled the quality goal for accuracy specified in ISO 15197:2003 and in ISO 15197:2013. The user-friendliness was rated as satisfactory. The percentage of technical errors fulfilled the goal ($\leq 2\%$).

Comments from the manufacturer

Roche Diagnostics has accepted the report without further comments.

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