# ACCU-CHEK® Aviva

***Meter and test strips***
***designed for glucose self-measurement***
***Manufactured by Roche Diagnostics GmbH***

## Report from the evaluation SKUP/2014/105

***organised by SKUP at the request of Roche Diagnostics Norge***

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# 1. Summary

**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 ≤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) 15197:2003[1] and ISO 15197:2013[2]. These quality goals state that at least 95% of the individual glucose results shall fall within the accuracy limits.

[1] ISO 15197:2003: <±0,83 mmol/L at glucose conc. <4,2 mmol/L or <±20% at glucose conc. ≥4,2 mmol/L
[2] ISO 15197:2013: <±0,83 mmol/L at glucose conc. <5,55 mmol/L or <±15% at glucose conc. ≥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 ≤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 (≤2%).

**Comments from the manufacturer**

Roche Diagnostics has accepted the report without further comments.

# 2. Abbreviations and Acronyms

| | |
|---|---|
| ADA | American Diabetes Association |
| BLS | Biomedical Laboratory Scientist |
| CI | Confidence Interval |
| C-NPU | Committee on Nomenclature, Properties and Units |
| CV | Coefficient of Variation |
| DEKS | Danish Institute of External Quality Assurance for Laboratories in Health Care |
| EQA | External Quality Assessment |
| Equalis | External quality assurance in laboratory medicine in Sweden |
| HDH | Haraldsplass Diaconal Hospital |
| HELFO | the Norwegian Health Economics Administration |
| ISO | International Organization for Standardization |
| NIST | National Institute of Standards & Technology |
| Noklus | Norwegian Quality Improvement of Primary Care Laboratories |
| SKUP | Scandinavian evaluation of laboratory equipment for primary health care |
| SRM | Standard Reference Material |

# 3. Quality goals

## 3.1. Analytical quality

Accu-Chek Aviva is designed for monitoring blood glucose, and the quality goals are set according to this.

*Precision*

According to the American Diabetes Association (ADA) the imprecision of new glucose devices must be less than 5% [1]. Other authors also recommend an imprecision of 5% or less [2-4].

*Accuracy*

The International Organization for Standardization (ISO)-standard 15197:2013 [5], is an international protocol for evaluating meters designed for glucose monitoring, and gives the following minimum acceptable accuracy requirement for measurements made by trained laboratory staff as well as measurements performed by persons with diabetes:
At least 95% of the individual glucose results shall fall within ±0,83 mmol/L of the results of the comparison method at glucose concentrations <5,55 mmol/L or within ±15% at glucose concentrations ≥5,55 mmol/L.

The previous version of the ISO-standard, ISO 15197:2003 [6], gave the following minimum acceptable accuracy requirement for measurements made by trained laboratory staff:
At least 95% of the individual glucose results shall fall within ±0,83 mmol/L of the results of the comparison method at glucose concentrations <4,2 mmol/L or within ±20% at glucose concentrations ≥4,2 mmol/L.

*Other analytical quality specifications*

In the Norwegian Health Economics Administration's (HELFO) standard protocol [7] the quality goal in ISO 15197:2003 is in use. In addition requirements with an allowable deviation of <±1,0 mmol/L at glucose concentrations <4,2 mmol/L or <±25% at glucose concentrations ≥4,2 mmol/L for measurements performed by persons with diabetes is given. The number of results within fixed limits of ±25% (for the end-users' measurements) and of ±10% (for the biomedical laboratory scientists' measurements) will be reported, but not further assessed in this report.
In Denmark the analytical quality goals for point of care glucose measurement systems are CV <4% and bias <3% [3, 4].

## 3.2. User-friendliness

The evaluation of user-friendliness is carried out by asking the participants (the intended users) to fill in a questionnaire about the user guide and the user-friendliness of Accu-Chek Aviva. Tables concerning assessment of time factors and assessment of quality control possibilities are filled in by SKUP. See section 5.5.

## 3.3. Technical errors

SKUP recommends that the percentage of "tests wasted" caused by technical errors should not exceed 2%.

## 3.4. Principles for the assessments

To qualify for an overall good assessment in a SKUP evaluation, the measurement system must show satisfactory analytical quality as well as satisfactory user-friendliness.

### 3.4.1. Assessment of the analytical quality

The analytical results are assessed according to the quality goals set for the evaluation.

*Precision*

The decision whether the achieved coefficient of variation (CV) fulfils the quality goal or not is made on a 5% significance level. The distinction between the ratings, and the assessment of precision according to the quality goal, are shown in table 1.

**Table 1.** The rating of precision

| Distinction between the ratings | Assessment according to the quality goal |
|---|---|
| The CV is lower than the quality goal (statistically significant) | The quality goal is fulfilled |
| The CV is lower than the quality goal (not statistically significant) | Most likely the quality goal is fulfilled |
| The CV is higher than the quality goal (not statistically significant) | Most likely the quality goal is not fulfilled |
| The CV is higher than the quality goal (statistically significant) | The quality goal is not fulfilled |

*Trueness*

The measured bias is given with a 95% confidence interval. The confidence interval is used for deciding if a difference between the two methods is statistically significant (two-tailed test, 5% significance level).

*Accuracy*

The accuracy is illustrated in difference-plots with limits for the allowable deviation according to the quality goal. The percentage of results within the limits is counted.
The accuracy is assessed as either fulfilling the quality goal or not fulfilling the quality goal.

### 3.4.2. Assessment of three lots

Separate lot calculations are not performed. The results achieved with the three lots are included in the assessment of accuracy in the difference plots. If distinct differences between the lots appear, this will be pointed out and discussed.

### 3.4.3. Assessment of the user-friendliness

The user-friendliness is assessed according to the answers and comments given in the questionnaire (see section 5.5.). For each question, the user must choose between three given ratings, as for instance satisfactory, intermediate or unsatisfactory. The response from the users is reviewed and summed up in section 5.5.

### 3.4.4. Assessment of the technical errors

The evaluating person registers the fraction of error codes and technical errors during the evaluation.

## 3.5. SKUP´s quality goals in this evaluation

As agreed upon when working on the protocol, the results from the evaluation of Accu-Chek Aviva are assessed against the following quality goals:

Repeatability CV ……. ≤5%

Allowable deviation in the individual result from the comparison method result (according to ISO 15197:2013)*
for glucose concentration <5,55 mmol/L ……..……≤±0,83 mmol/L
for glucose concentration ≥5,55 mmol/L …….≤±15%
Required percentage of individual results within the allowable deviations……..≥95%

Fraction of technical errors ……..…… ≤2%

User-friendliness, overall rating…… Satisfactory

* The results in the evaluation will also be assessed against the quality goal in ISO 15197:2003.

# 4. Materials and methods

## 4.1. Definition of the measurand

The Committee on Nomenclature, Properties and Units (C-NPU) describes clinical laboratory tests in a database [8]. In the NPU-database the specifications for the measurand in this evaluation are as shown in table 2.

**Table 2**. NPU-specifications

| NPU code | Name of test according to NPU | Unit |
|---|---|---|
| NPU22089 | Plasma(capillary Blood) — Glucose; substance concentration | mmol/L |

The term glucose will be used for the measurand. Another variable measured in the evaluation is haematocrit (%).

## 4.2. The evaluated measurement system; Accu-Chek Aviva

The Accu-Chek Aviva system is designed for blood glucose testing performed by persons with diabetes or by health care professionals. The system consists of an Accu-Chek Aviva meter (figure 1) and dry reagent test strips. The glucose measurement is based on biosensor technology. Glucose dehydrogenase converts glucose to gluconolactone. The enzyme in the reaction is a mutant variant of quinoprotein glucose dehydrogenase. The enzyme is modified to prevent maltose interference. The system is automatically switched on and calibrated when a test strip is inserted. The measurement starts when a sufficient amount of blood is drawn into the test strip. According to the manufacturer, it is possible to use blood samples from alternative sites on Accu-Chek Aviva. Accu-Chek Aviva reports plasma glucose values.


**Figure 1.** Accu-Chek Aviva meter

A summary of technical data from the manufacturer is given in table 3. For more technical data about Accu-Chek Aviva, name of the manufacturer and the suppliers in the Scandinavian countries, see attachment 2 and 3. For product information, see attachment 4.

**Table 3**. Technical data from the manufacturer

| **Technical data for Accu-Chek Aviva** | |
|---|---|
| Sample material | Capillary blood |
| Sample volume | 0,6 µL |
| Measuring time | 5 seconds |
| Measuring range | 0,6 — 33,3 mmol/L |
| Tolerated haematocrit range | 10 — 65% |
| Storage capacity | 500 results |
| Electrical power supply | One 3-volt lithium battery (CR 2032 coin cell battery) |

## 4.3. The selected comparison method

A selected comparison method is a fully specified method which, in the absence of a Reference method, serves as a common basis for the comparison of an evaluated method.

### 4.3.1. The selected comparison method in this evaluation

The selected comparison method in the evaluation of Accu-Chek Aviva is the routine method for quantitative determination of glucose in human serum and plasma at the laboratory at Haraldsplass Diaconal Hospital (HDH) in Bergen, hereafter called "the comparison method". The method is a photometric glucose hexokinase method implemented on the Cobas 6000 System from Roche Diagnostics. The glucose method on HDH is accredited according to NS-EN ISO 15189 (2007) by Norwegian Accreditation. The laboratory can document good analytical quality of the method through participation in an external analytical quality assessment program. The laboratory guaranties a reproducibility CV ≤3%.

### 4.3.2. Verification of the analytical quality of the comparison method

*Precision*

The repeatability of the comparison method was estimated from duplicate measurements of capillary patient samples.

*Trueness*

To document the trueness of the comparison method, the standard reference material (SRM 965b) from National Institute of Standards & Technology, NIST, was used [9]. SRM 965b consists of ampoules with human serum with certified concentrations of glucose at four levels with given uncertainties.

*Internal quality control*

Autonorm Human Liquid Control Solutions at two levels from SERO AS were included in the measuring series in this evaluation.

*External quality control*

Human serum controls, produced by Norwegian Quality Improvement of Primary Care Laboratories (Noklus), with glucose concentrations at two levels were analysed. These controls have target values determined with an isotope-dilution gas chromatography/mass spectrometry method in a Reference laboratory in Belgium [10]. The target value is given with an expanded uncertainty of 1,5 - 2% (k=2). The controls are used in Noklus' External Quality Assessment (EQA) program.

## 4.4. The evaluation

### 4.4.1. Planning of the evaluation

*Background for the evaluation*

Mette Engebretsen, Roche Diagnostics Norge, applied to SKUP in April 2013 for an evaluation of an updated Accu-Chek Aviva meter and the Accu-Chek Aviva test strips with maltose independence chemistry (MIC). The updated meter was expected ready for use in late autumn 2013. Roche and SKUP agreed that the practical work with the evaluation should start in January 2014.

*Protocol, contract and agreement*

In December 2013, the protocol for the evaluation was approved, and Roche and SKUP signed a contract for the evaluation. The laboratory at HDH agreed to analyse the samples for the comparison method.

*Preparations and training program*

SKUP started the preparations for the evaluation in October 2013. Marianne Risa, Camilla Eide Jacobsen and Grete Monsen, biomedical laboratory scientists (BLSs), are familiar with several blood glucose measurement systems, also with earlier versions of the Accu-Chek Aviva meter. Further training from Roche was not necessary. The meters and test strips for the evaluation were received in December 2013. Shortly after, the equipment was prepared for distribution among the diabetes patients. The practical work with the evaluation was carried out in February and March 2014.

### 4.4.2. Evaluation sites and persons involved

An overview of persons responsible for the evaluation is given in table 4.

**Table 4.** Persons responsible for various parts of the evaluation

| Name | Title | Place | Responsibility |
|---|---|---|---|
| Mette Engebretsen | Market Access & Business Development Manager | Roche Diagnostics Norge | Ordered the evaluation<br>Contact person |
| Grete Monsen | BLS<br>SKUP Organisation Secretary | SKUP/Noklus | Responsible for the evaluation<br>Practical work with the evaluation |
| Marianne Risa | BLS | SKUP/Noklus | Preparations for the evaluation<br>Practical work with the evaluation<br>Statistical calculations<br>Author of the report |
| Camilla Eide Jacobsen | BLS<br>Master of Science | SKUP/Noklus | Practical work with the evaluation |
| Tom Atle Jermstad<br>Henriette Mohn Soldal | BLSs | Laboratory at HDH | Practical work with the comparison method |

### 4.4.3. The evaluation model

*The SKUP evaluation*

SKUP evaluations are based upon the fundamental guidelines in the book "*Utprøving av analyseinstrumenter*" [11]. SKUP's model for glucose user-evaluation is based on a standard model used by HELFO for test strip reimbursement in Norway [7].

*The model for the evaluation of Accu-Chek Aviva*

The evaluation consisted of two parallel parts. One part of the evaluation was carried out under standardised and optimal conditions by laboratory educated personnel at Noklus. This part documents the quality of the system under conditions as favourable as possible for achieving good analytical quality.

Diabetes patients performed the other part of the evaluation in order to demonstrate the analytical quality of Accu-Chek Aviva achievable by the users. The diabetes patients received the device and instructions by mail. Three lots of test strips from separate productions were distributed evenly between the participants (random distribution). The model for the evaluation among diabetes patients is shown in figure 2.

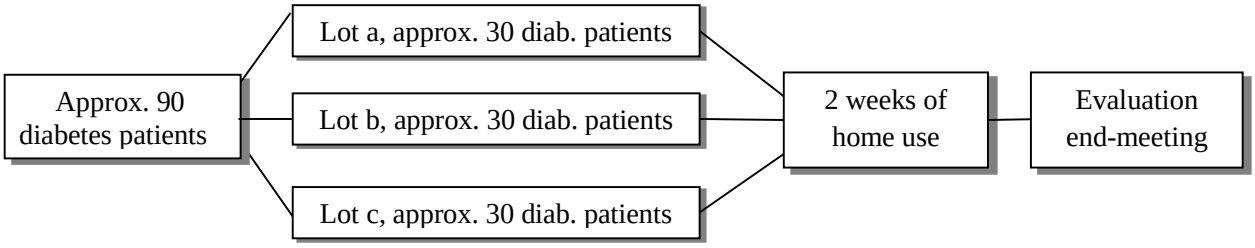


**Figure 2.** The model for the evaluation among the intended users

*The aim of the evaluation*

The evaluation of Accu-Chek Aviva comprises the following studies:

- Estimation of the analytical quality under standardised and optimal conditions, performed by BLSs in a hospital environment
    - Estimation of imprecision
    - Assessment of accuracy according to the quality goal given in ISO 15197:2003
    - Assessment of accuracy according to the quality goal given in ISO 15197:2013
- Estimation of the analytical quality among approximately 90 diabetes patients
- Assessment of the variation between three lots of test strips
- Examination of the degree of haematocrit interference
- Evaluation of the user-friendliness of Accu-Chek Aviva and the user manual

### 4.4.4. Recruitment, selection and characteristics of the diabetes patients

*Recruitment*

The diabetes patients were recruited by a brochure and by mail inquiry sent to the members of the local branch of The Norwegian Diabetes Association.

*Selection*

The participants were selected at random, but with the criterion to get variety in the group according to gender, diabetes type, age and how often the participants performed blood glucose measurements.

*Characteristics of the diabetes patients that completed the evaluation*

The Accu-Chek Aviva glucose meter was tested in use by 54 men and 35 women with diabetes. The average age of the participants was 59 years (range 22 – 75). A total of 30 participants had Type1 diabetes, 57 had Type2 diabetes and two participants did not know their type of diabetes. The group included diabetes patients from a range of self-monitoring frequencies, i.e. diabetes patients who perform self-monitoring often and those who perform self-monitoring less frequently.

### 4.4.5. The evaluation procedure under standardised and optimal conditions

The BLSs used three Accu-Chek Aviva blood glucose meters in the evaluation. For all the diabetes patients two measurements were performed with each of the three meters (totally six measurements for each diabetes patient). On meter A, lot 491918 (called lot a) was used, on meter B, lot 491938 (called lot b) was used, and on meter C, lot 491943 (called lot c) was used for all the measurements. All possibilities for disturbance of, and interference with, the measurements were tried kept at a minimum.

*Internal analytical quality control*

Meter A, B and C were checked with the manufacturer's control solutions, Control 1 and Control 2, every day in use. The control ranges were 1,7 – 3,3 mmol/L and 14,1 – 19,1 mmol/L, respectively.

*Blood sampling*

All samples for Accu-Chek Aviva, as well as the glucose samples for the comparison method, were collected from finger capillaries. The blood samples for the duplicate measurements on Accu-Chek Aviva were mainly collected from the same finger prick. The BLS wiped off the first drop of blood before the first measurement and between the two sets of duplicates (meter A, B and C). In order to reduce the possible change in the glucose concentration during the sampling sequence, the sampling time ought not to exceed 10 minutes.

The blood sampling and analysis were carried out in the following order:

1. The BLS took a first sample for the comparison method
2. The BLS took samples for meter A, B, C, A, B and C (the order of the measurements on meter A, B and C was changed between each diabetes patient)
3. The diabetes patient took duplicate samples for his/her assigned meter
4. The BLS took a second sample for the comparison method
5. The BLS took a venous sample for haematocrit

*Handling of the samples for the comparison method*
The samples for the comparison method were taken from a finger capillary using Microvette Li-heparin tubes (300 µL) from Sarstedt. The samples were centrifuged immediately for three minutes at 10 000 g, and plasma was separated. The plasma samples were frozen directly and stored at minus 80°C at Noklus until the analysis took place (according to the storing procedure for the standard reference material from NIST [9]).
The samples were analysed during three days in March 2014.

*Comparison method results*
Two capillary samples were collected of each diabetes patient for measurement on the comparison method. The second sample was analysed in duplicate. The duplicate results were used for calculations of imprecision. The mean value of the first sample result and the average result of the second sample is referred to as the mean result of the comparison method. The mean result of the comparison method is an estimate of the true glucose value in the samples.

*Stability of the glucose concentration during the sampling time*
The stability of the glucose concentration during sampling was supervised by means of the capillary samples for the comparison method taken at the start and in the end of each sampling sequence. Based on experience from several previous glucose meter user-evaluations, a stability criteria with a change <10% between the first and second comparative result is regarded as reasonable.

*Measurement of haematocrit*
Haematocrit may influence on blood glucose measurements. A venous sample was collected from each diabetes patient (voluntarily) and the haematocrit was measured within six hours with Advia2120i or Cell-Dyn Sapphire at the laboratory at HDH.

*Recording of results*
All results were registered in a form provided by SKUP and signed by the evaluator. If one of the meters showed an error code while analysing a sample, a new measurement was made. Error codes were recorded.

*Evaluation of the user-friendliness*
The BLS looked for any defects and deficiencies or whether there was anything with the system that did not function optimally. They provided a description in the form of keywords about the system and the user guide.

### 4.4.6. Evaluation among the intended users
The diabetes patients received the Accu-Chek Aviva meter by mail, along with test strips, lancet pen, lancets, user manual and an information letter with explanations regarding what to do with the Accu-Chek Aviva device during the period at home.

*Use of Accu-Chek Aviva at home*
The diabetes patients used Accu-Chek Aviva at home for approximately two weeks. They used Accu-Chek Aviva in addition to their own glucose meter, and they continued to carry out self-measurements with their own meter as usual. During the first week the diabetes patients familiarised themselves with the new device. Each diabetes patient had approximately 25 test strips disposal to measure his/her blood glucose with Accu-Chek Aviva this first week. If

preferred, they could perform the measurements at the same time as performing measurements with their own meter. During the second week, the diabetes patients performed duplicate measurements on Accu-Chek Aviva on five different days. The results were recorded on a provided form for documentation of the training efforts.

*Internal analytical quality control*
To document correct functioning of the Accu-Chek Aviva meters used by the diabetes patients, the BLS checked the meters with the control solution when the diabetes patients met at the evaluation meeting.

*The evaluation meeting*
After the two-week practice period at home, the diabetes patients met, one by one, for the evaluation meeting. The diabetes patients brought their assigned Accu-Chek Aviva to the meeting. Before the samples were collected, the device was equilibrated to room temperature while the diabetes patients filled in the questionnaire regarding user-friendliness of Accu-Chek Aviva and the user manual. The diabetes patients pricked themselves and made duplicate blood glucose measurements on their assigned meter. For sampling procedure see section 4.4.5. Most of them used the distributed Accu-Chek FastClix lancing device for the blood sampling. The measurements were performed with the test strips delivered to the diabetes patients for the evaluation. The results were registered. Error codes were recorded.

# 5. Results and discussion

Statistical expressions and calculations used by SKUP are shown in attachment 5.

## 5.1. Number of samples

A total of 92 diabetes patients signed up for the evaluation and 89 of them completed. In total three participants withdrew from the evaluation for various reasons. A venous sample for haematocrit was collected from 88 of the 89 participants.

### 5.1.1. The glucose concentration stability during sampling

Out of 89 pairs of results measured on the comparison method, one showed a difference >10% which means that this participant had an unstable glucose concentration during the sampling sequence time. This applied to ID 52.

### 5.1.2. Excluded or missing results

The following results are missing or excluded:

- ID 52 had a deviation of >10% between the first and second sample for the comparison method. All results from ID 52 were removed before the assessment of accuracy and haematocrit influence, and before the calculation of bias.
- ID 86 had no hematocrit result.

### 5.1.3. Failed measurements

The BLSs performed 729 measurements (6 measurements x 89 patients + 195 quality control measurements) on Accu-Chek Aviva. On one occasion blood was drawn into the test strip but no result was achieved (no error code). One test strip failed to draw blood into the test strip but the system gave no error code. This gives a total of two of the BLSs' measurements that failed because of technical errors.

The diabetes patients performed 178 measurements (2 measurements x 89 patients). Five of these measurements failed with error code "E-7" (electronic error). In addition one test strip was not sufficiently filled with blood, yet the system gave no error code. This gives a total of six of the diabetes patients' measurements that failed due to technical errors.

Total percentage of technical errors was: ((2 + 6) / (729 + 178)) x 100 = 0,9%

*Discussion*

The percentage of technical errors was 0,9% and the goal (≤2%) was fulfilled.

### 5.1.4. Concentration range of the samples

The concentration range for the samples in this evaluation was:

- Glucose concentration (the comparison method): 3,8 – 22,1 mmol/L
- Haematocrit: 34 – 51%

## 5.2. Analytical quality of the selected comparison method

### 5.2.1. Internal quality control

In daily operation of the comparison method, the analytical quality of the method is monitored with internal quality control solutions at two levels of glucose concentrations. All control results from the evaluation period (three days) were within the limits the laboratory has set for the controls. The laboratory shows a reproducibility CV of approximately 1,4% in daily use.

### 5.2.2. The precision of the comparison method

*Repeatability*

To achieve a measure for the repeatability of the comparison method, one capillary sample collected of each diabetes patient was analysed in duplicate. The repeatability CV of the comparison method with a 90% confidence interval (CI) is shown in table 5. The raw data is shown in attachment 6 (only available for the producer).

**Table 5.** Repeatability of the comparison method with capillary blood samples

| Glucose level, mmol/L | n | Excluded results | Mean value glucose, mmol/L | CV (90% CI), % |
|---|---|---|---|---|
| <7 | 16 | 0 | 6,1 | 1,3 (1,0 — 1,8) |
| 7 — 10 | 39 | 0 | 8,1 | 1,1 (1,0 — 1,4) |
| >10 | 34 | 0 | 13,4 | 1,3 (1,1 — 1,6) |

*Discussion*

The repeatability CV for the comparison method was between 1,1 and 1,3%.

### 5.2.3. The trueness of the comparison method

In order to demonstrate the trueness of the comparison method, SRM 965b standards purchased from NIST, were analysed. The agreement between the comparison method and the NIST-standards is shown in table 6.

**Table 6.** Standard Reference Material (SRM 965b) measured on the comparison method

| SRM 965b | Date | Certified glucose concentration, (uncertainty) mmol/L | n | Mean value glucose, mmol/L | Deviation from target value, % |
|---|---|---|---|---|---|
| Level 1 | 21.03.14 | **1,836** (1,809 — 1,863) | 5 | 1,91 | +3,8 |
| | 26.03.14 | | 5 | 1,87 | +2,0 |
| | **Total** | | **10** | **1,89** | **+2,9** |
| Level 2 | 21.03.14 | **4,194** (4,135 — 4,253) | 5 | 4,36 | +4,0 |
| | 26.03.14 | | 5 | 4,33 | +3,3 |
| | **Total** | | **10** | **4,35** | **+3,6** |
| Level 3 | 21.03.14 | **6,575** (6,481 — 6,669) | 5 | 6,70 | +1,9 |
| | 26.03.14 | | 5 | 6,67 | +1,5 |
| | **Total** | | **10** | **6,69** | **+1,7** |
| Level 4 | 21.03.14 | **16,35** (16,15 — 16,55) | 5 | 16,50 | +0,9 |
| | 26.03.14 | | 5 | 16,52 | +1,0 |
| | **Total** | | **10** | **16,51** | **+1,0** |

*Comments*

Table 6 shows that the glucose results for three of the NIST-standards were just above the upper uncertainty limit, while the glucose results for level 4 were close to the upper uncertainty limit. All results from the comparison method were therefore adjusted according to the certified NIST-targets. The adjustment was carried out by means of inverse calibration [12, 13] by the following regression equation: $\mathbf{y = 0,9947x - 0,0804}$.

Further on in the report, whenever any result from the comparison method is presented, the result has already been adjusted according to this equation.

To verify the trueness of the adjusted comparison method results, human serum controls produced by Noklus, were analysed. The agreement between the comparison method and target values from the Reference laboratory in Belgium is shown in table 7.

**Table 7**. Trueness of the comparison method

| **Control** | **Date** | **Target value glucose, (expanded uncertainty) mmol/L** | **n** | **Mean value glucose, mmol/L** | **Deviation from target value, %** |
|---|---|---|---|---|---|
| Noklus 1 | 21.03.14 | **5,71** | 5 | 5,79 | 1,4 |
| | 26.03.14 | (5,62 — 5,80) | 5 | 5,80 | 1,6 |
| | **Total** | | **10** | **5,80** | **1,5** |
| Noklus 2 | 21.03.14 | **11,94** | 5 | 12,09 | 1,3 |
| | 26.03.14 | (11,70 — 12,18) | 5 | 12,04 | 0,8 |
| | **Total** | | **10** | **12,06** | **1,0** |

*Discussion*

The comparison method gave glucose values in agreement with the glucose values from the Reference laboratory in Belgium.

## 5.3. Analytical quality of Accu-Chek Aviva

### 5.3.1. Internal quality control

The Accu-Chek Aviva meters used by the diabetes patients were checked with the manufacturer's control solution (Control 2) by the BLS at the evaluation meeting. All results were within the control range. The reproducibility CV was 1,8% (n=89). The Accu-Chek Aviva meters used by the BLSs were checked with control solutions every day they were used. All results were within the control range. The reproducibility CV was 3,1% for Control 1 (n=53) and 1,7% for Control 2 (n=53). Raw data is shown in attachment 7.

### 5.3.2. Comparison of the 1st and 2nd measurement

Two capillary samples were collected of each diabetes patient for measurements on meter A, meter B and meter C at the evaluation meeting. In addition, the diabetes patients took two capillary samples for measurements on their assigned meter at the evaluation meeting. The formula used for the calculation of repeatability (formula 1) is shown in attachment 5. The results have been checked to meet the imposed condition for using the formula (data not shown).

### 5.3.3. The precision of Accu-Chek Aviva

*Repeatability under standardised and optimal conditions in a hospital environment*

The repeatability obtained by the BLSs with capillary blood samples is shown in table 8. The results are sorted and divided into three glucose levels according to the first measurement on Accu-Chek Aviva. Raw data is shown in attachment 8.

**Table 8.** Repeatability, Accu-Chek Aviva. Results achieved by the BLSs

| Accu-Chek Aviva | Glucose level, mmol/L | n | Excluded results | Mean value glucose, mmol/L | CV (90% CI), % |
|---|---|---|---|---|---|
| Meter A | <7 | 28 | 0 | 6,1 | 2,4 (2,0 — 3,1) |
| Meter B | <7 | 26 | 0 | 6,1 | 3,2 (2,6 — 4,2) |
| Meter C | <7 | 30 | 0 | 6,2 | 2,6 (2,1 — 3,2) |
| Meter A | 7 — 10 | 31 | 0 | 8,1 | 3,0 (2,5 — 3,9) |
| Meter B | 7 — 10 | 35 | 0 | 8,2 | 4,3 (3,7 — 5,4) |
| Meter C | 7 — 10 | 30 | 0 | 8,1 | 2,4 (2,0 — 3,1) |
| Meter A | >10 | 30 | 0 | 12,8 | 3,2 (2,6 — 4,1) |
| Meter B | >10 | 28 | 0 | 13,1 | 2,8 (2,3 — 3,7) |
| Meter C | >10 | 29 | 0 | 12,9 | 3,6 (3,0 — 4,6) |

An account of the number of samples, and excluded and missing results, is given in section 5.1.

*Repeatability obtained by the diabetes patients*
The repeatability obtained by the diabetes patients with capillary blood samples is shown in table 9. The results are sorted and divided into three glucose levels according to the first measurement on Accu-Chek Aviva. Raw data is shown in attachment 9.

**Table 9.** Repeatability, Accu-Chek Aviva. Results achieved by the diabetes patients

| Glucose level, mmol/L | n | Excluded results | Mean value glucose, mmol/L | CV (90% CI), % |
|---|---|---|---|---|
| <7 | 22 | 0 | 6,2 | 4,7 (3,7 — 6,3) |
| 7 — 10 | 38 | 0 | 8,1 | 6,0 (5,0 — 7,4) |
| >10 | 29 | 0 | 13,1 | 4,3 (3,6 — 5,6) |

An account of the number of samples, and excluded and missing results, is given in section 5.1.

*Discussion, repeatability*
The principles for the assessment of the analytical quality are described in section 3.4.1.

The repeatability CV obtained under standardised and optimal conditions (table 8) was between 2,4 and 4,3%. The quality goal of a CV ≤5% was fulfilled for all measurements except for measurements with a glucose level 7 – 10 mmol/L on meter B. For these measurements the upper CI value was > 5%. Most likely the quality goal was fulfilled also for these measurements.

The repeatability CV obtained at Noklus when the measurements were performed by the diabetes patients (table 9) was between 4,3 and 6,0%. For glucose level <7 mmol/L and >10 mmol/L the repeatability CV was <5%, but the upper CI values were >5%. Most likely the quality goal was fulfilled. For glucose level 7 - 10 mmol/L the repeatability CV was 6,0% and the lower CI value 5%. The quality goal was most likely not fulfilled.

*Measurements at home*
The results the diabetes patients obtained at home document the diabetes patients training efforts. Repeatability was not calculated based on these results.

### 5.3.4. The trueness of Accu-Chek Aviva

The mean deviation of Accu-Chek Aviva results from the comparison method results (bias) was calculated from the results achieved by the BLSs. The results are sorted and divided into three glucose levels according to the mean results on the comparison method. The bias of Accu-Chek Aviva with three lots of test strips is shown in table 10.

**Table 10.** Bias of Accu-Chek Aviva. Results achieved by the BLSs.

| Accu-Chek Aviva (lot number of test strips) | Glucose level Comparison method, mmol/L | n | Excluded results | Mean glucose Comparison method, mmol/L | Mean glucose Accu-Chek Aviva, mmol/L | Bias (95% CI), mmol/L |
|---|---|---|---|---|---|---|
| 491918 (lot a) | <7 | 18 | 0 | 6,1 | 5,8 | −0,3 ((−0,4) — (−0,2)) |
| | 7 — 10 | 36 | 0 | 8,0 | 7,5 | −0,6 ((−0,7) — (−0,5)) |
| | >10 | 34 | 0 | 13,2 | 12,3 | −0,9 ((−1,0) — (−0,7)) |
| 491938 (lot b) | <7 | 18 | 0 | 6,1 | 5,9 | −0,1 ((−0,2) — (−0,0)) |
| | 7 — 10 | 36 | 0 | 8,0 | 7,5 | −0,5 ((−0,6) — (−0,4)) |
| | >10 | 34 | 0 | 13,2 | 12,5 | −0,7 ((−0,9) — (−0,5)) |
| 491943 (lot c) | <7 | 18 | 0 | 6,1 | 5,9 | −0,2 ((−0,3) — (−0,1)) |
| | 7 — 10 | 36 | 0 | 8,0 | 7,4 | −0,6 ((−0,7) — (−0,5)) |
| | >10 | 34 | 0 | 13,2 | 12,4 | −0,8 ((−1,1) — (−0,6)) |

An account of the number of samples, and excluded and missing results, is given in section 5.1.

*Discussion*

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 ((−2,5%) — (−6,5%)). An assessment of the three lots of test strips is given in section 5.3.6.

### 5.3.5. The accuracy of Accu-Chek Aviva

To evaluate the accuracy of the results on Accu-Chek Aviva, the agreement between Accu-Chek Aviva and the comparison method is illustrated in two accuracy plots. The plots show the deviation of single measurement results on Accu-Chek Aviva from the true value, and give a picture of both random and systematic errors, reflecting the total measuring error on Accu-Chek Aviva. The accuracy is demonstrated for the first measurements of the paired results, only.

The accuracy of Accu-Chek Aviva meter A/lot a, meter B/lot b and meter C/lot c, under standardised and optimal measuring conditions is shown in figure 3. The accuracy of Accu-Chek Aviva, as measured by the diabetes patients is shown in figure 4. The accuracy is summarised in table 11.

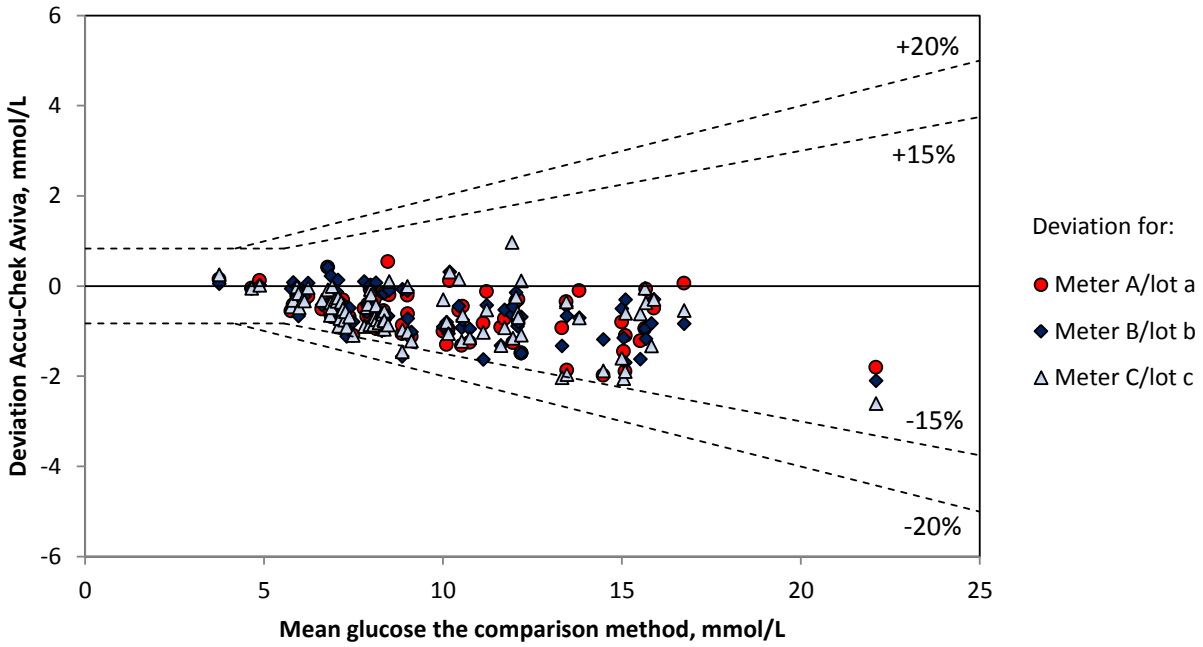


**Figure 3.** Accuracy. Accu-Chek Aviva meter A/lot a (marked with symbol ●), meter B/lot b (marked with symbol ♦) and meter C/lot c (marked with symbol △) under standardised and optimal measuring conditions. The x-axis represents the mean result of the comparison method. The y-axis shows the difference between the first measurement on Accu-Chek Aviva and the mean result of the comparison method. Stippled lines represent quality goal limits set in ISO 15197:2003 (within ±0,83 mmol/L for glucose concentrations <4,2 mmol/L and within ±20% for glucose concentrations ≥4,2 mmol/L) and quality goal limits set in ISO 15197:2013 (within ±0,83 mmol/L for glucose concentrations <5,55 mmol/L and within ±15% for glucose concentrations ≥5,55 mmol/L).
Number of results (n) = 88.

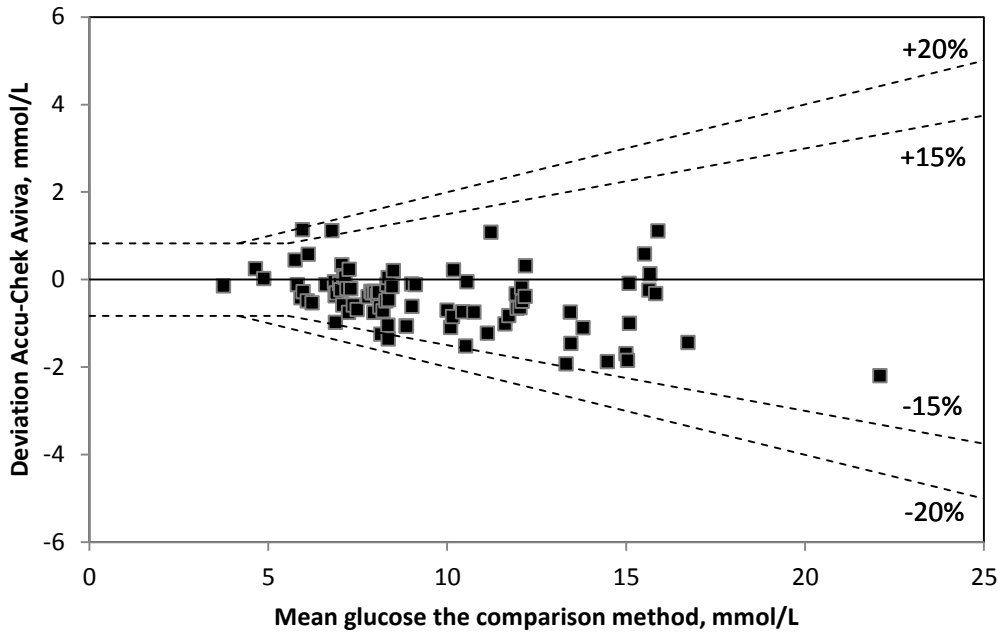


**Figure 4.** Accuracy. The diabetes patients' self-measurements on Accu-Chek Aviva (three lots of test strips). The x-axis represents the mean result of the comparison method. The y-axis shows the difference between the first measurement on Accu-Chek Aviva and the mean result of the comparison method. Stippled lines represent quality goal limits set in ISO 15197:2003 (within ±0,83 mmol/L for glucose concentrations <4,2 mmol/L and within ±20% for glucose concentrations ≥4,2 mmol/L) and quality goal limits set in ISO 15197:2013 (within ±0,83 mmol/L for glucose concentrations <5,55 mmol/L and within ±15% for glucose concentrations ≥5,55 mmol/L).
Number of results (n) = 88.

**Table 11.** Accuracy of Accu-Chek Aviva

| Measurement performed by | Lot | n | Percentage of results within given limits, % | | | |
|---|---|---|---|---|---|---|
| | | | "Adjusted ISO"[1] | ISO 15197:2003[2] | ISO 15197:2013[3] | Fixed limit ±10% |
| BLSs | a | 88 | | 100 | 100 | 80 |
| | b | 88 | | 100 | 98 | 82 |
| | c | 88 | | 100 | 98 | 72 |
| Diabetes patients at Noklus | a, b, c | 88 | 100 | 100 | 95 | 81 |

[1]"Adjusted ISO": <±1,0 mmol/L at conc. <4,2 mmol/L or <±25% at conc. ≥4,2 mmol/L
[2] ISO 15197:2003: <±0,83 mmol/L at conc. <4,2 mmol/L or <±20% at conc. ≥4,2 mmol/L
[3] ISO 15197:2013: <±0,83 mmol/L at conc. <5,55 mmol/L or <±15% at conc. ≥5,55 mmol/L
An account of the number of samples, and excluded and missing results, is given in section 5.1.

*Discussion*
Figure 3 and 4 show that the Accu-Chek Aviva glucose results were slightly lower than the results from the comparison method. The summing up in table 11 shows that 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 their results were within the accuracy quality limits specified in ISO 15197:2013. The accuracy quality goals were fulfilled. Table 11 also shows the number of results within fixed limit of ±10% and within "adjusted ISO". These results are for information only.

### 5.3.6. Bias with three lots of test strips

The three lots of test strips gave systematic lower glucose results than the comparison method (table 10). Figure 3 shows the same tendency. No deviations between the three lots of test strips appear.

## 5.4. Effect of haematocrit

According to the technical specifications, glucose measurements on Accu-Chek Aviva are not influenced by haematocrit values from 10 to 65%. To measure the effect of haematocrit on Accu-Chek Aviva, a venous sample for haematocrit was collected of the diabetes patients at the evaluation meeting. The investigation of the effect is based on the measurements on Accu-Chek Aviva meter A (lot a) under standardised and optimal measuring conditions. The effect of haematocrit is shown with a trend-line and a regression equation in figure 5. The raw data is shown in attachment 10.

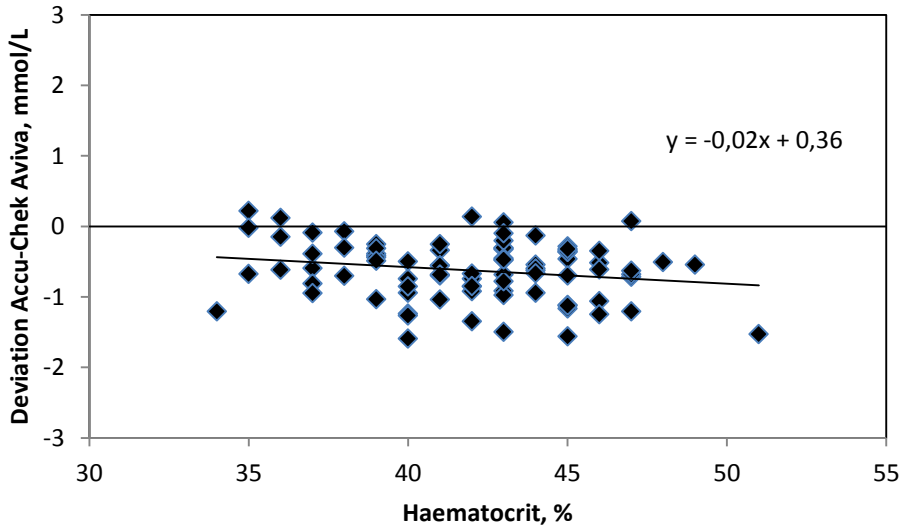


**Figure 5.** The effect of haematocrit on glucose measurements on Accu-Chek Aviva meter A (lot a) measured under standardised and optimal conditions. The x-axis shows the haematocrit value in percent. The y-axis shows the difference in glucose concentration between Accu-Chek Aviva and the mean result of the comparison method in mmol/L. Number of results (n) = 87.

*Discussion*

The slope of the trend-line in figure 5 is (−0,02), with a 95% CI from (−0,048) to (+0,001). The slope is not statistically significant different from zero. Glucose measurements on Accu-Chek Aviva in the evaluation were not affected by haematocrit values within the range 34 − 51%.

## 5.5. Evaluation of user-friendliness

### 5.5.1. Questionnaire to the evaluators

The most important response regarding user-friendliness comes from the users themselves. The end-users often emphasize other aspects than those pointed out by more extensively trained laboratory personnel.

When attending the evaluation meeting, the diabetes patients filled in a questionnaire about the user-friendliness of the manual and the operation facilities of the meter. The BLS was available for clarifying questions, and there was free space for commenting. Each diabetes patient was first asked whether he/she had used the user manual. If the answer was no, they were to ignore the questions regarding the user manual.

The questionnaire is divided into four sub-areas:

Table A) Rating of the information in the manual
Table B) Rating of operation facilities
Table C) Rating of time factors
Table D) Rating of quality control

The end-users filled in table A and B. SKUP filled in table C and D, and filled in addition in topics marked with grey colour in table A and B.

In the tables the first column shows what is up for consideration. The other columns show the rating options as well as the number and percentage of diabetes patients who chose this alternative (for table A and B). The last row in each table summarises the total rating in the table. The total rating is an overall assessment by SKUP of the described property, and not necessarily the arithmetic mean of the rating in the rows. Consequently, a single poor rating can justify an overall poor rating, if this property seriously influences on the user-friendliness of the system.

*Comment*
In this evaluation, the user-friendliness was assessed by 89 diabetes patients and the three BLSs.

**Table A.** Rating of the information in the manual

| **Topic** | **Assessment** Number of responses (%) | **Assessment** Number of responses (%) | **Assessment** Number of responses (%) | **Assessment** Number of responses (%) |
|---|---|---|---|---|
| General impression (74/74 responses) | Satisfactory 61 (82%) | Intermediate 12 (16%) | Unsatisfactory 1 (1%) | No opinion 0 (0%) |
| Description/illustration regarding specimen collection (73/74 responses) | Satisfactory 61 (84%) | Intermediate 12 (16%) | Unsatisfactory 0 (0%) | No opinion 0 (0%) |
| Description of how to perform a blood glucose measurement with the meter (73/74 responses) | Satisfactory 66 (90%) | Intermediate 7 (10%) | Unsatisfactory 0 (0%) | No opinion 0 (0%) |
| Description of how to insert a test strip (74/74 responses) | Satisfactory 68 (92%) | Intermediate 6 (8%) | Unsatisfactory 0 (0%) | No opinion 0 (0%) |
| Explanation of error sources (73/74 responses) | Satisfactory 44 (60%) | Intermediate 16 (22%) | Unsatisfactory 2 (3%) | No opinion 11 (15%) |
| Fault-tracing / Troubleshooting (72/74 responses) | Satisfactory 44 (61%) | Intermediate 15 (21%) | Unsatisfactory 1 (1%) | No opinion 12 (17%) |
| Readability / Clarity of presentation (73/74 responses) | Satisfactory 55 (75%) | Intermediate 13 (18%) | Unsatisfactory 4 (5%) | No opinion 1 (1%) |
| All in all, how satisfied are you with the user manual (74/74 responses) | Satisfied 63 (85%) | Intermediate 10 (14%) | Unsatisfied 1 (1%) | No opinion 0 (0%) |
| Table of contents | **Satisfactory** | Intermediate | Unsatisfactory | |
| Preparations / Pre-analytic procedures | **Satisfactory** | Intermediate | Unsatisfactory | |
| Measurement principle | Satisfactory | Intermediate | **Unsatisfactory**[1] | |
| Keyword index | **Satisfactory** | Intermediate | Unsatisfactory | |
| Available in Danish, Norwegian and Swedish | **Satisfactory** | Intermediate | Unsatisfactory | |
| **Total rating by SKUP** | **Satisfactory** | | | |

[1] Measuring principle not mentioned in the manual.

*Comment*
A total of 74 diabetes patients had used the manual.

*Positive comments*

A total of 18 participants had one or more positive comments regarding the user manual. The most often reported positive comments were:

1. The manual is easily understood (6)
2. The manual has good explanations/illustrations (6)
3. The manual is clear and easy to follow (4)
4. The manual is easily read (3)

*Negative comments*

A total of 15 participants had one or more negative comments regarding the user manual. The most often reported negative comments were:

1. The manual has small letters (7)
2. A short version of the manual should be available (4)
3. The manual is too big/comprehensive/detailed (3)

**Table B.** Rating of operation facilities

| **Topic** | **Assessment** Number of responses (%) | **Assessment** Number of responses (%) | **Assessment** Number of responses (%) | **Assessment** Number of responses (%) |
|---|---|---|---|---|
| All in all, to operate the meter (87/89 responses) | Easy 79 (91%) | Intermediate 8 (9%) | Difficult 0 (0%) | No opinion 0 (0%) |
| To perform a blood glucose measurement with the meter (88/89 responses) | Easy 83 (94%) | Intermediate 5 (6%) | Difficult 0 (0%) | No opinion 0 (0%) |
| To insert a test strip (87/89 responses) | Easy 81 (93%) | Intermediate 6 (7%) | Difficult 0 (0%) | No opinion 0 (0%) |
| To fill the test strip with blood (88/89 responses) | Easy 80 (91%) | Intermediate 8 (9%) | Difficult 0 (0%) | No opinion 0 (0%) |
| To read the figures in the display (88/89 responses) | Easy 83 (94%) | Intermediate 2 (2%) | Difficult 3 (3%) | No opinion 0 (0%) |
| The device, design and handling (85/89 responses) | Satisfactory 68 (80%) | Intermediate 17 (20%) | Unsatisfactory 0 (0%) | No opinion 0 (0%) |
| Sources of errors, error codes (84/89 responses) | Satisfactory 37 (44%) | Intermediate 14 (17%) | Unsatisfactory 3 (4%) | No opinion 30 (36%) |
| Cleaning / Maintenance; scale and time (86/89 responses) | Satisfactory 49 (57%) | Intermediate 9 (10%) | Unsatisfactory 0 (0%) | No opinion 28 (33%) |
| Hygiene, when using the test (87/89 responses) | Satisfactory 71 (82%) | Intermediate 8 (9%) | Unsatisfactory 3 (3%) | No opinion 5 (6%) |
| Size and weight of package (88/89 responses) | Satisfactory 55 (63%) | Intermediate 24 (27%) | Unsatisfactory 9 (10%) | No opinion 0 (0%) |
| To prepare the test/instrument (87/89 responses) | Satisfactory 74 (85%) | Intermediate 13 (15%) | Unsatisfactory 0 (0%) | No opinion 0 (0%) |
| To prepare the sample (83/89 responses) | Satisfactory 65 (78%) | Intermediate 12 (14%) | Unsatisfactory 1 (1%) | No opinion 5 (6%) |
| Specimen volume (87/89 responses) | Satisfactory 70 (80%) | Intermediate 12 (14%) | Unsatisfactory 3 (3%) | No opinion 2 (3%) |
| Number of procedure steps (87/89 responses) | Satisfactory 74 (85%) | Intermediate 12 (14%) | Unsatisfactory 0 (0%) | No opinion 1 (1%) |
| Instrument/test design (83/89 responses) | Satisfactory 62 (75%) | Intermediate 20 (24%) | Unsatisfactory 1 (1%) | No opinion 0 (0%) |
| Storage conditions for tests, unopened package | **+15 to +30°C** | +2 to +8°C | –20°C | |
| Storage conditions for tests, opened package | **+15 to +30°C** | +2 to +8°C | –20°C | |
| Environmental aspects: waste handling | **No precautions** | Sorted waste | Special precautions | |
| Intended users | **Health care personnel or patients** | Laboratory experienced | BLS | |
| **Total rating by SKUP** | **Satisfactory** | | | |

*Positive comments*

A total of 41 participants had one or more positive comments regarding the operation facilities of Accu-Chek Aviva. The most often reported positive comments were:

1. Comments regarding the use of the meter (22); the meter is easy to use, has short measuring time, needs a small amount of blood
2. The meter has a good design, is good to hold, small (11)
3. Comments regarding the lancing device (11); positive with six lancets in a drum, adjustable, the lancing device is good
4. Comments regarding the display (10); a big and clear display, large numbers, easy to read the result
5. Comments regarding the test strips (6); blood is easily drawn into the test strip, the test strip has good shape, easy to see when the test strip is filled with blood, easy to take the test strip out of the box
6. It is a "good" meter (5)

*Negative comments*

A total of 48 participants had one or more negative comments regarding the operation facilities of Accu-Chek Aviva. The most often reported negative comments were:

1. Comments regarding the test strips (19); difficult to get only one test strip out of the box, difficult to get a test strip out of the box without touching the other test strips in the box, single test strips
2. The meter is too big (14)
3. Comments regarding the lancing device (9); the lancing device is difficult to use, hard to get enough blood, it ought not be possible to use the same lancet needle more than once
4. Comments regarding the display (6); no light in the display, not good enough contrast between the numbers and the background
5. Comments regarding the meter's soft case (5); the case is narrow, the elastic band in the case covers the display, the case seems to have a poor quality and probably short durability

**Table C.** Rating of time factors (filled in by SKUP)

| **Topic** | **Assessment** | **Assessment** | **Assessment** |
|---|---|---|---|
| Required training time | **<2 hours** | 2 to 8 hours | >8 hours |
| Duration of preparations / Pre-analytical time | **<6 min.** | 6 to 10 min. | >10 min. |
| Duration of analysis | **<10 min.** | 10 to 20 min. | >20 min. |
| Stability of test, unopened package | **>5 months** | 3 to 5 months | <3 months |
| Stability of test, opened package | **>30 days** | 14 to 30 days | <14 days |
| Stability of quality control material, unopened | **>5 months** | 3 to 5 months | <3 months |
| Stability of quality control material, opened | **>6 days or disposable** | 2 to 6 days | ≤1 day |
| **Total rating by SKUP** | **Satisfactory** | | |

**Table D.** Rating of quality control (filled in by SKUP)

| **Topic** | **Assessment** | **Assessment** | **Assessment** |
|---|---|---|---|
| Reading of the internal quality control | **Satisfactory** | Intermediate | Unsatisfactory |
| Usefulness of the internal quality control | **Satisfactory** | Intermediate | Unsatisfactory |
| External quality control | **Satisfactory** | Intermediate | Unsatisfactory |
| **Total rating by SKUP** | **Satisfactory** | | |

The control material is stable until the given experiation date if stored at +2 to +32°C. The stability of the control material is three months after opening the vial.

### 5.5.2. The biomedical laboratory scientists' evaluation

The BLSs' evaluation of Accu-Chek Aviva is shown in table E.

**Table E.** The BLSs' evaluation of Accu-Chek Aviva

| | Positive comments | Negative comments |
|---|---|---|
| Control solution | – Stable even if it had been opened several times<br>– Controls in different concentration levels | – Not commutable<br>– A control solution at normal concentration level is desirable |
| To operate the meter | – Easy to use<br>– Short measuring time<br>– Small blood volume<br>– The blood is easily drawn into the test strip | – Difficult to get only one test strip out of the test strip box when the box was full<br>– Difficult to get a test strip out of the box without touching the other test strips in the box |
| The user manual | – Simple and easy to understand<br>– The manual is clear and easy to follow | – No information telling how low/high your blood glucose can be if you get the result LO/HI.<br>– A short version should be available |

### 5.5.3. Assessment of the user-friendliness

The overall feed-back from the participants in this evaluation was positive.

As seen in table A most of the users were satisfied with the information given in the manual.

Table B shows that the users were mostly satisfied with the operation facilities.

Time factors and quality control possibilities are assessed as satisfactory (table C and D).

The BLSs found the device easy to use, but commented that the test strips could be difficult to get out of the test strip box without touching the other test strips.

*Conclusion*

Based on the assessments from the diabetes patients and SKUP, the user-friendliness of Accu-Chek Aviva was rated as satisfactory.

# 6. References


1. American Diabetes Association. Self-monitoring of blood glucose. *Diabetes Care* 1996; **19** (suppl 1): 62 – 66.
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6. In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus, ed. ISO 15197:2003.
7. www.helfo.no (menu Helsepersonell – Leverandører).
8. http://www.ifcc.org/ifcc-scientific-division/sd-committees/c-npu/npusearch/
9. National Institute of Standards and Technology, Certificate of Analysis, Standard Reference Material® 965b, Glucose in Frozen Human Serum. www.nist.gov
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12. Krutchkoff RG. Classical and inverse regression methods of calibration. *Technometrics* 1967; **9** (3): 425 – 439.
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# The organisation of SKUP

*Scandinavian evaluation of laboratory equipment for primary health care*, *SKUP*, is a co-operative commitment of Noklus[1] in Norway, DAK-E[2] in Denmark, and Equalis[3] in Sweden. SKUP was established in 1997 at the initiative of laboratory medicine professionals in the three countries. SKUP is led by a Scandinavian *steering committee* and the secretariat is located at Noklus in Bergen, Norway.

*The purpose of* SKUP is to improve the quality of near patient testing in Scandinavia by providing objective and supplier-independent information on analytical quality and user-friendliness of laboratory equipment. This information is generated by organising SKUP *evaluations*.

SKUP offers manufacturers and suppliers evaluations of equipment for primary health care and also of devices for self-monitoring. Provided the equipment is not launched onto the Scandinavian market, it is possible to have a confidential pre-marketing evaluation. The company requesting the evaluation pays the actual testing costs and receives in return an impartial evaluation.

There are *general guidelines* for all SKUP evaluations and for each evaluation a specific *SKUP protocol* is worked out in co-operation with the manufacturer or their representatives. SKUP signs *contracts* with the requesting company and the evaluating laboratories. A *complete evaluation* requires one part performed by experienced laboratory personnel as well as one part performed by the intended users.

Each evaluation is presented in a *SKUP report* to which a unique *report code* is assigned. The code is composed of the acronym SKUP, the year and a serial number. A report code, followed by an asterisk (*), indicates a special evaluation, not complete according to the guidelines, e.g. the part performed by the intended users was not included in the protocol. If suppliers use the SKUP name in marketing, they have to refer to www.skup.nu and to the report code in question. For this purpose the company can use a logotype available from SKUP containing the report code.

SKUP reports are published at www.skup.nu.

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[1] Noklus (Norwegian Quality Improvement of Primary Care Laboratories) is an organisation founded by Kvalitetsforbedringsfond III (Quality Improvement Fund III), which is established by The Norwegian Medical Association and the Norwegian Government. Noklus is professionally linked to "Seksjon for Allmennmedisin" (Section for General Practice) at the University of Bergen, Norway.

[2] SKUP in Denmark is placed in Nordsjællands Hospital. SKUP in Denmark reports to DAK-E (Danish Quality Unit of General Practice), an organisation that is supported by KIF (Foundation for Quality and Informatics) and Faglig udvalg (Professional Committee), which both are supported by DR (The Danish Regions) and PLO (The Organisation of General Practitioners in Denmark).

[3] Equalis AB (External quality assurance in laboratory medicine in Sweden) is a limited company in Uppsala, Sweden, owned by "Sveriges Kommuner och Landsting" (Swedish Association of Local Authorities and Regions), "Svenska Läkaresällskapet" (Swedish Society of Medicine) and IBL (Swedish Institute of Biomedical Laboratory Science).

# Facts about Accu-Chek Aviva

This form is filled in by Roche Diagnostics.

**Table 1. Basic facts**

| | |
|---|---|
| Name of the measurement system: | Accu-Chek® Aviva blood glucose monitoring system |
| Dimensions and weight: | Width: 52 mm Depth: 94 mm Height: 21 mm Weight: 59g |
| Components of the measurement system: | Accu-Chek® Aviva test strips, Accu-Chek® Aviva controls, Accu-Chek® FastClix lancing device |
| Measurand: | Glucose |
| Sample material: | Capillary, Venous, Arterial and Neonate |
| Sample volume: | 0.6µL |
| Measuring principle: | Mutant variant of quinoprotein glucose dehydrogenase (Mut. Q-GDH), electrochemical |
| Traceability: | NIST standard |
| Calibration: | The system is calibrated with venous blood containing various glucose concentrations. The reference values are obtained using a validated test method. This test method is referenced to the hexokinase method and is traceable to a NIST standard. |
| Measuring range: | 10 mg/dL-600 mg/dL (0.6 mmol/L-33.3 mmol/L) |
| Linearity: | yes |
| Measurement duration: | 5 seconds |
| Operating conditions: | 8 to 44° C |
| Electrical power supply: | 1 battery, 3V type 2032 |
| Recommended regular maintenance: | The meter automatically tests its own system every time you turn it on and lets you know if something is wrong. Keep the meter free of dust |
| Package contents: | Meter, carry case, lancing device, lancets and instructions for use |
| Necessary equipment not included in the package: | Accu-Chek® Aviva test strips and Accu-Chek® Aviva controls |

**Table 2. Post analytical traceability**

| | |
|---|---|
| Is input of patient identification possible? | No |
| Is input of operator identification possible? | No |

| | |
|---|---|
| Can the instrument be connected to a bar-code reader? | No |
| Can the instrument be connected to a printer? | No |
| What can be printed? | N/A |
| Can the instrument be connected to a PC? | Yes via software and cable |
| Can the instrument communicate with LIS (Laboratory Information System)?<br>If yes, is the communication bidirectional? | No |
| What is the storage capacity of the instrument and what is stored in the instrument? | Up to 500 total results, plus 20 control tests |
| Is it possible to trace/search for measurement results? | Yes |

**Table 3. Facts about the reagent/test strips/test cassettes**

| | |
|---|---|
| Name of the reagent/test strips/test cassettes: | Accu-Chek® Aviva test strips |
| Stability<br>in unopened sealed vial: | 18 months |
| Stability<br>in opened vial: | Test strips remain stable up to expiry date |
| Package contents: | Test strips and package insert |

**Table 4. Quality control**

| | |
|---|---|
| Electronic self check: | Yes |
| Recommended control materials and volume: | Level 1 and Level 2; 2.5 mL per bottle |
| Stability<br>in unopened sealed vial: | 24 months |
| Stability<br>in opened vial: | 3 months from the date you open the bottle or until the date on the bottle label, whichever comes first |
| Package contents: | Controls and package insert |

# Information about manufacturer, retailers and marketing

This form is filled in by Roche Diagnostics.

**Table 1. Marketing information**

| | |
|---|---|
| Manufacturer: | Roche Diagnotsics GmbH<br>Sandhofer Straße 116<br>68305 Mannheim, Germany |
| Retailers in Scandinavia: | Denmark: Mediq, Reamed, Nomeco Apotekerne<br><br>Norway: NMD, Alliance HealthCare, Apokjeden<br><br>Sweden: Mediq, OneMed |
| In which countries is the system marketed: | Globally Scandinavia x Europe x |
| Date for start of marketing the system in Scandinavia: | December 2013 |
| Date for CE-marking: | July 26, 2013 |
| In which Scandinavian languages is the manual available: | Finnish, Norwegian, Danish and Swedish |

# Product information, Accu-Chek Aviva

*Accu-Chek Aviva serial numbers*
A total of 92 Accu-Chek Aviva blood glucose meters were used in this evaluation. Three meters (serial no. SN45900082354 (meter A), SN45900075396 (meter B) and SN45900066017 (meter C)) were used by the biomedical laboratory scientists under the standardised and optimal conditions.

*Accu-Chek Aviva test strips*

| | |
|---|---|
| Lot 491918 | Expiry 2015-03-31 |
| Lot 491938 | Expiry 2015-03-31 |
| Lot 491943 | Expiry 2015-03-31 |

*Accu-Chek Aviva Control Solutions (Control 1 and Control 2)*

| | |
|---|---|
| Lot 30100632 | Expiry 2015-06 |
| Target value Control 1 | 1,7 – 3,3 mmol/L |
| Target value Control 2 | 14,1 – 19,1 mmol/L |

*Blood sampling device used by the biomedical laboratory scientists (single use only)*
Accu-Chek Softclix Pro
Accu-Chek Softclix Pro Lancets

*Blood sampling device used by the diabetes patients*
The diabetes patients could choose whether to use the distributed Accu-Chek FastClix lancing device (with Accu-Chek FastClix lancets), or the lancet device they usually use.

Accu-Chek FastClix lancets

| | |
|---|---|
| Lot WPB 702 | Expiry 2017-08 |

# Statistical expressions and calculations

This chapter with standardised text deals with the statistical expressions and calculations used by SKUP. The statistical calculations will change according to the type of evaluation. The descriptions in this document are valid for evaluations of quantitative methods with results on the ratio scale.

## Statistical terms and expressions

The definitions in this section come from the ISO/IEC Guide 99; International Vocabulary of Metrology, VIM [a].

### Precision

*Definition: Precision is the closeness of agreement between measured quantity values obtained by replicate measurements on the same or similar objects under stated specified conditions.*

Precision is measured as *imprecision*. Precision is descriptive in general terms (good, poor e.g.), whereas the imprecision is expressed by means of the standard deviation (SD) or coefficient of variation (CV). SD is reported in the same unit as the analytical result. CV is usually reported in percent.

To be able to interpret an assessment of precision, the precision conditions must be defined.
*Repeatability* is the precision of consecutive measurements of the same component carried out under identical measuring conditions (within the measuring series).
*Reproducibility* is the precision of discontinuous measurements of the same component carried out under changing measuring conditions over time.

### Trueness

*Definition: Trueness is the closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value.*

Trueness is inversely related to systematic measurement error. Trueness is measured as *bias*. Trueness is descriptive in general terms (good, poor e.g.), whereas the bias is reported in the same unit as the analytical result or in percent.

### Accuracy

*Definition: Accuracy is the closeness of agreement between a measured quantity value and the true quantity value of a measurand.*

Accuracy is not a quantity and cannot be expressed numerically. A measurement is said to be more accurate when it offers a smaller measurement error. Accuracy can be illustrated in a difference-plot. Accuracy is descriptive in general terms (good, poor e.g.).

a. ISO/IEC Guide 99:2007, International vocabulary of metrology – Basic and general concepts and associated terms, VIM, 3rd edition, JCGM 200:2008

## Statistical calculations

### Statistical outliers

The criterion promoted by Burnett [b] is used for the detection of outliers. The model takes into consideration the number of observations together with the statistical significance level for the test. The significance level is set to 5%. The segregation of outliers is made with repeated truncations, and all results are checked. Where the results are classified according to different concentration levels, the outlier-testing is carried out at each level separately. Statistical outliers are excluded from the calculations.

### Calculation of imprecision

The precision of the evaluated method is assessed by use of paired measurements of genuine patient sample material. The results are divided into three concentration levels, and the estimate of imprecision is calculated for each level separately, using the following formula [c,d]:

$$SD = \sqrt{\frac{\sum d^2}{2n}}$$

$d$ = difference between two paired measurements (formula 1)
$n$ = number of differences

This formula is used when the standard deviation can be assumed reasonable constant across the concentration interval. If the coefficient of variation is more constant across the concentration interval, the following formula is preferred:

$$CV = \sqrt{\frac{\sum (d/m)^2}{2n}}$$

$m$ = mean of paired measurements (formula 2)

The two formulas are based on the differences between paired measurements. The calculated standard deviation or CV is still a measure of the imprecision of single values. The imposed condition for using the formulas is that there is no systematic difference between the 1st and the 2nd measurement of the pairs. The CV is given with a 90% confidence interval.

### Calculation of bias

The mean deviation (bias) at different concentration levels is calculated based on results achieved under optimal measuring conditions. A paired t-test is used with the mean values of the duplicate results on the comparison method and the mean values of the duplicate results on the evaluated method. The mean difference is shown with a 95% confidence interval.

### Assessment of accuracy

The agreement between the evaluated method and the comparison method is illustrated in a difference-plot. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on the evaluated method and the mean value of the duplicate results on the comparison method. The number of results within the quality goal limits is counted and assessed.


b. Burnett RW. Accurate estimation of standard deviations for quantitative methods used in clinical chemistry. Clinical Chemistry 1975; **21** (13): 1935 – 1938.

c. Saunders E. Tietz textbook of clinical chemistry and molecular diagnostics, 2006. Chapter 14, Linnet K., Boyd J. Selection and analytical evaluation of methods – with statistical techniques. Elsevier Saunders ISBN 0-7216-0189-8.

d. Fraser C.G. Biological variation: From principles to practice, 2006. Chapter 1, The Nature of Biological Variation. AACC Press ISBN 1-890883-49-2.

**Raw data glucose, internal quality control, Accu-Chek Aviva**

| Accu-Chek Aviva Control Solutions | Lot-no | Expiry | Target value Glucose (mmol/L) |
|---|---|---|---|
| Control 1 | 30100632 | 2015-06 | 1,7 – 3,3 |
| Control 2 | | | 14,1 – 19,1 |

**Accu-Chek Aviva Control 1 and Control 2 analysed on the biomedical laboratory scientists' meters A, B and C**

| Date | Meter | Accu-Chek Aviva Control 1 Glucose (mmol/L) | Accu-Chek Aviva Control 2 Glucose (mmol/L) |
|---|---|---|---|
| 11.02.2014 | A | 2,4 | 16,6 |
| 11.02.2014 | B | 2,4 | 16,8 |
| 11.02.2014 | C | 2,5 | 17,1 |
| 12.02.2014 | A | 2,5 | 16,6 |
| 12.02.2014 | B | 2,4 | 16,8 |
| 12.02.2014 | C | 2,4 | 16,6 |
| 13.02.2014 | A | 2,4 | 16,8 |
| 13.02.2014 | B | 2,4 | 17,1 |
| 13.02.2014 | C | 2,4 | 17,0 |
| 14.02.2014 | A | 2,4 | 16,9 |
| 14.02.2014 | B | 2,4 | 16,9 |
| 14.02.2014 | B | 2,6 | 17,0 |
| 14.02.2014 | C | 2,5 | 16,4 |
| 18.02.2014 | A | 2,4 | 16,9 |
| 18.02.2014 | B | 2,6 | 16,8 |
| 18.02.2014 | C | 2,5 | 17,1 |
| 19.02.2014 | A | 2,5 | 17,8 |
| 19.02.2014 | B | 2,4 | 17,3 |
| 19.02.2014 | C | 2,5 | 17,4 |
| 20.02.2014 | A | 2,4 | 16,9 |
| 20.02.2014 | B | 2,5 | 17,1 |
| 20.02.2014 | C | 2,5 | 17,2 |
| 21.02.2014 | A | 2,4 | 16,9 |
| 21.02.2014 | B | 2,4 | 17,1 |
| 21.02.2014 | C | 2,6 | 17,4 |
| 21.02.2014 | C | 2,4 | 17,3 |
| 25.02.2014 | A | 2,4 | 16,3 |

| Date | Meter | Accu-Chek Aviva Control 1 Glucose (mmol/L) | Accu-Chek Aviva Control 2 Glucose (mmol/L) |
|---|---|---|---|
| 25.02.2014 | B | 2,5 | 17,5 |
| 25.02.2014 | C | 2,6 | 17,4 |
| 04.03.2014 | A | 2,4 | 16,8 |
| 04.03.2014 | B | 2,4 | 17,0 |
| 04.03.2014 | C | 2,5 | 16,9 |
| 05.03.2014 | A | 2,4 | 17,0 |
| 05.03.2014 | B | 2,5 | 16,6 |
| 05.03.2014 | C | 2,6 | 17,0 |
| 06.03.2014 | A | 2,4 | 16,9 |
| 06.03.2014 | B | 2,5 | 17,0 |
| 06.03.2014 | C | 2,6 | 16,9 |
| 07.03.2014 | A | 2,4 | 16,9 |
| 07.03.2014 | B | 2,5 | 17,0 |
| 07.03.2014 | C | 2,6 | 17,0 |
| 11.03.2014 | A | 2,4 | 16,8 |
| 11.03.2014 | B | 2,5 | 17,3 |
| 11.03.2014 | C | 2,5 | 16,9 |
| 12.03.2014 | A | 2,4 | 16,6 |
| 12.03.2014 | B | 2,4 | 16,9 |
| 12.03.2014 | C | 2,6 | 17,4 |
| 13.03.2014 | A | 2,4 | 17,3 |
| 13.03.2014 | B | 2,4 | 16,9 |
| 13.03.2014 | C | 2,6 | 17,4 |
| 14.03.2014 | A | 2,4 | 16,6 |
| 14.03.2014 | B | 2,5 | 17,3 |
| 14.03.2014 | C | 2,5 | 17,2 |

**Measurements on meter A are performed with lot 491918.**
**Measurements on meter B are performed with lot 491938.**
**Measurements on meter C are performed with lot 491943.**

**Accu-Chek Aviva Control 2 analysed on the diabetes patients' meters**

| ID | Lot-no Accu-Chek Aviva test strips | Accu-Chek Aviva Control 2 Glucose (mmol/L) |
|---|---|---|
| 1 | a | 16,9 |
| 2 | a | 16,8 |
| 3 | a | 16,5 |
| 4 | a | 16,6 |
| 6 | a | 17,0 |
| 8 | a | 16,9 |
| 9 | a | 16,8 |
| 10 | a | 16,8 |
| 11 | a | 17,1 |
| 13 | a | 17,3 |
| 14 | a | 16,4 |
| 16 | a | 16,1 |
| 18 | a | 16,5 |
| 19 | a | 17,1 |
| 22 | a | 16,5 |
| 23 | a | 16,5 |
| 26 | a | 16,9 |
| 29 | a | 16,4 |
| 30 | a | 16,9 |
| 34 | a | 16,9 |
| 36 | b | 17,1 |
| 37 | a | 16,9 |
| 39 | b | 17,0 |
| 40 | b | 16,6 |
| 42 | b | 16,6 |
| 43 | a | 16,6 |
| 44 | a | 16,8 |
| 47 | b | 17,0 |
| 48 | a | 16,8 |
| 49 | b | 17,0 |
| 52 | b | 16,6 |
| 53 | a | 17,3 |
| 54 | a | 17,0 |
| 55 | a | 16,6 |
| 56 | a | 16,9 |
| 57 | b | 16,8 |
| 58 | a | 16,8 |
| 59 | b | 16,8 |
| 60 | b | 17,3 |
| 61 | c | 16,9 |
| 62 | a | 16,6 |
| 63 | b | 17,0 |
| 64 | b | 17,1 |
| 65 | b | 16,0 |
| 66 | b | 17,3 |

| ID | Lot-no Accu-Chek Aviva test strips | Accu-Chek Aviva Control 2 Glucose (mmol/L) |
|---|---|---|
| 68 | b | 16,8 |
| 69 | b | 16,5 |
| 70 | c | 16,7 |
| 73 | c | 16,7 |
| 76 | b | 16,5 |
| 79 | b | 17,5 |
| 80 | b | 16,8 |
| 81 | b | 16,8 |
| 82 | b | 16,7 |
| 84 | c | 17,0 |
| 85 | b | 17,3 |
| 86 | b | 17,8 |
| 87 | b | 16,9 |
| 89 | b | 16,9 |
| 90 | c | 17,5 |
| 91 | c | 17,4 |
| 93 | b | 16,7 |
| 94 | c | 17,1 |
| 98 | b | 16,8 |
| 99 | b | 16,9 |
| 101 | c | 17,1 |
| 103 | c | 17,4 |
| 105 | b | 16,6 |
| 109 | c | 16,9 |
| 110 | c | 16,8 |
| 111 | c | 17,0 |
| 118 | c | 16,9 |
| 120 | c | 16,6 |
| 126 | c | 16,9 |
| 128 | c | 17,1 |
| 130 | c | 17,3 |
| 131 | c | 17,0 |
| 135 | c | 16,6 |
| 137 | c | 17,4 |
| 140 | c | 17,1 |
| 143 | c | 17,1 |
| 144 | c | 16,9 |
| 146 | c | 17,1 |
| 148 | c | 16,4 |
| 150 | c | 16,8 |
| 152 | c | 16,7 |
| 154 | c | 16,8 |
| 155 | c | 16,3 |
| 158 | c | 17,2 |

**Lot a**: **491918**
**Lot b**: **491938**
**Lot c**: **491943**

**Raw data haematocrit**

| ID | Haematocrit |
|---|---|
| 1 | 0,43 |
| 2 | 0,46 |
| 3 | 0,42 |
| 4 | 0,39 |
| 6 | 0,43 |
| 8 | 0,39 |
| 9 | 0,45 |
| 10 | 0,47 |
| 11 | 0,35 |
| 13 | 0,43 |
| 14 | 0,42 |
| 16 | 0,45 |
| 18 | 0,41 |
| 19 | 0,40 |
| 22 | 0,43 |
| 23 | 0,51 |
| 26 | 0,40 |
| 29 | 0,44 |
| 30 | 0,37 |
| 34 | 0,44 |
| 36 | 0,48 |
| 37 | 0,43 |
| 39 | 0,40 |
| 40 | 0,39 |
| 42 | 0,44 |
| 43 | 0,45 |
| 44 | 0,45 |
| 47 | 0,47 |
| 48 | 0,43 |
| 49 | 0,43 |
| 52 | 0,41 |
| 53 | 0,41 |
| 54 | 0,38 |
| 55 | 0,45 |
| 56 | 0,40 |
| 57 | 0,43 |
| 58 | 0,45 |
| 59 | 0,42 |
| 60 | 0,41 |
| 61 | 0,40 |
| 62 | 0,44 |
| 63 | 0,42 |
| 64 | 0,43 |
| 65 | 0,44 |
| 66 | 0,47 |

| ID | Haematocrit |
|---|---|
| 68 | 0,39 |
| 69 | 0,34 |
| 70 | 0,41 |
| 73 | 0,45 |
| 76 | 0,39 |
| 79 | 0,43 |
| 80 | 0,37 |
| 81 | 0,45 |
| 82 | 0,42 |
| 84 | 0,40 |
| 85 | 0,38 |
| 86 | No result |
| 87 | 0,36 |
| 89 | 0,38 |
| 90 | 0,44 |
| 91 | 0,43 |
| 93 | 0,46 |
| 94 | 0,45 |
| 98 | 0,43 |
| 99 | 0,35 |
| 101 | 0,45 |
| 103 | 0,41 |
| 105 | 0,47 |
| 109 | 0,43 |
| 110 | 0,41 |
| 111 | 0,39 |
| 118 | 0,47 |
| 120 | 0,36 |
| 126 | 0,42 |
| 128 | 0,39 |
| 130 | 0,42 |
| 131 | 0,49 |
| 135 | 0,43 |
| 137 | 0,37 |
| 140 | 0,46 |
| 143 | 0,45 |
| 144 | 0,41 |
| 146 | 0,46 |
| 148 | 0,46 |
| 150 | 0,37 |
| 152 | 0,36 |
| 154 | 0,37 |
| 155 | 0,35 |
| 158 | 0,40 |

# *SKUP-info*

***Accu-Chek Aviva blodsukkerapparat fra Roche Diagnostics***
***Sammendrag fra en utprøving i regi av SKUP***

***Konklusjon***
**Accu-Chek Aviva viste en presisjon (CV) mellom 2,4 og 4,3 % når målingene ble utført av laboratorieutdannet personale og mellom 4,3 og 6,0 % når målingene ble utført av personer med diabetes. Resultatene fra Accu-Chek Aviva var systematisk litt lavere ((-0,1) – (-0,9) mmol/L) enn resultatene fra en anerkjent sykehusmetode. Kvalitetsmålet fra ISO 15197:2013, som tillater avvik opp til ± 15 % fra en anerkjent metode for måling av glukose, ble oppnådd. Hematokrit, i området 34 – 51 %, påvirket ikke glukosemålingene på Accu-Chek Aviva. De fleste brukerne var fornøyde med apparatet og med brukermanualen.**

***Accu-Chek Aviva*** er beregnet til egenmåling av blodsukker. Systemet er produsert av Roche Diagnostics, og består av Accu-Chek Aviva blodsukkerapparat og Accu-Chek Aviva teststrimler. Apparatet kalibreres automatisk når man setter inn en teststrimmel. Det kreves 0,6 µL blod til hver måling. Målingen tar 5 sekunder. Accu-Chek Aviva kan lagre 500 resultat.

***Utprøvingen*** ble utført under optimale betingelser av laboratorieutdannet personale og blant 89 personer med diabetes. Alle deltakerne fikk apparat og instruksjon tilsendt pr. post. Deltakerne brukte Accu-Chek Aviva hjemme i to uker og møtte deretter til et avslutningsmøte. Glukoseresultatene fra Accu-Chek Aviva ble sammenlignet med resultatene fra en anerkjent sykehusmetode. Tre lot av teststrimler ble benyttet.

***Resultater***
Accu-Chek Aviva viste en presisjon (CV) mellom 2,4 og 4,3 % når målingene ble utført av laboratorieutdannet personale og mellom 4,3 og 6,0 % når målingene ble utført av deltakerne. Resultatene fra Accu-Chek Aviva var systematisk litt lavere ((-0,1) – (-0,9) mmol/L) enn resultatene fra en anerkjent sykehusmetode. Kvalitetsmålet fra ISO 15197:2013, som tillater avvik opp til ± 15 % fra en anerkjent metode for måling av glukose, ble oppnådd både for målinger utført av laboratorieutdannet personale og for målinger utført av deltakerne. Hematokrit, i området 34 – 51 %, påvirket ikke glukosemålingene på Accu-Chek Aviva.

***Brukervennlighet***
De fleste deltakerne syntes Accu-Chek Aviva var enkel å bruke, og de var fornøyde med apparatet. De fleste deltakerne som hadde lest i brukermanualen, var fornøyde med denne.

***Tilleggsinformasjon***
Den fullstendige rapporten fra utprøvingen av Accu-Chek Aviva, SKUP/2014/105, finnes på SKUPs nettside www.skup.nu. Opplysninger om pris fås ved å kontakte leverandør. Laboratoriekonsulentene i Noklus kan gi nyttige råd om analysering av glukose på legekontor. De kan også orientere om det som finnes av alternative metoder/utstyr.

# List of previous SKUP evaluations

*Summaries and complete reports from the evaluations are found at www.skup.nu. In addition, SKUP reports are published at www.skup.dk, where they are rated according to the national Danish quality demands for near patient instruments used in primary health care. SKUP summaries are translated into Italian by Centre for Metrological Traceability in Laboratory Medicine (CIRME), and published at http://users.unimi.it/cirme. SKUP as an organisation has no responsibility for publications of SKUP results on these two web-sites.*

## The 30 latest SKUP evaluations

| Evaluation no. | Component | Instrument/testkit | Producer |
|---|---|---|---|
| SKUP/2014/105 | Glucose[1] | Accu-Chek Aviva | Roche Diagnostics |
| SKUP/2013/87 | Glucose[1] | Wellion Calla Light | Med Trust Handelsges.m.b.H |
| SKUP/2013/100 | Glucose[1] | mylife Unio | Bionime Corporation |
| SKUP/2013/97 | NT-proBNP | Cobas h 232 POC system | Roche Diagnostics GmbH |
| SKUP/2013/92 | CRP | Eurolyser smart 700/340 | Eurolyser Diagnostica GmbH |
| SKUP/2013/99* | Glucose | Accu-Chek Mobile | Roche Diagnostics |
| SKUP/2013/98* | Glucose | Accu-Chek Aviva | Roche Diagnostics |
| SKUP/2013/85 | Glucose, β-Ketone | Nova StatStrip | Nova Biomedical Corporation, USA |
| SKUP/2013/96 | Hemoglobin | DiaSpect Hemoglobin T | DiaSpect Medical GmbH |
| SKUP/2013/68 | Allergens | ImmunoCap Rapid | Phadia AB Marknadsbolag Sverige |
| SKUP/2012/95 | Glucose[1] | Mendor Discreet | Mendor Oy |
| SKUP/2012/94 | Glucose[1] | Contour XT | Bayer Healthcare |
| SKUP/2012/91 | HbA1c | Quo-Test A1c | Quoient Diagnostics Ltd |
| SKUP/2011/93* | Glucose | Accu-Chek Performa | Roche Diagnostics |
| SKUP/2011/90 | CRP | *i*-Chroma | BodiTech Med. Inc. |
| SKUP/2011/84* | PT-INR | Simple Simon PT and MixxoCap | Zafena AB |
| SKUP/2011/86 | Glucose[1] | OneTouch Verio | LifeScan, Johnson & Johnson |
| SKUP/2011/77 | CRP | *Confidential* | |
| SKUP/2011/70* | CRP | smartCRP system | Eurolyser Diagnostica GmbH |
| SKUP/2010/83* | Glucose | *Confidential* | |
| SKUP/2010/78 | HbA1c | In2it | Bio-Rad |
| SKUP/2010/80 | PT (INR) | INRatio2 | Alere Inc. |
| SKUP/2010/89* | Glucose | FreeStyle Lite | Abbott Laboratories |
| SKUP/2010/88* | HbA1c | *Confidential* | |
| SKUP/2010/82* | Glucose, protein, blood, leukocytes, nitrite | Medi-Test URYXXON Stick 10 urine test strip and URYXXON Relax urine analyser | Macherey-Nagel GmBH & Co. KG |
| SKUP/2010/81* | Glucose | mylife PURA | Bionime Corporation |
| SKUP/2010/67 | Allergens | *Confidential* | |
| SKUP/2010/79* | Glucose, protein, blood, leukocytes, nitrite | CombiScreen 5SYS Plus urine test strip and CombiScan 100 urine analyser | Analyticon Biotechnologies AG |
| SKUP/2010/73 | Leukocytes | HemoCue WBC | HemoCue AB |
| SKUP/2009/71 | Glucose[1] | GlucoMen LX | A. Menarini Diagnostics |

*A report code followed by an asterisk indicates that the evaluation is not complete according to SKUP guidelines, since the part performed by the intended users was not included in the protocol, or the evaluation is a follow-up of a previous evaluation, or the evaluation is a special request from the supplier.

[1] Including a user-evaluation among diabetes patients