Accu-Chek Mobile

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

Report from the evaluation SKUP/2013/99*

organised by SKUP at the request of Roche Diagnostics Scandinavia AB

* This evaluation is a follow-up of a previous evaluation

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The report was written by SKUP, April - May 2013.
For more details about SKUP, see attachment 1.
Main author was Marianne Risa, SKUP in Norway.

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Attachment 6 and 8 are included only in the copy to Roche Diagnostics Scandinavia AB.

1. Summary

Background for the evaluation
Accu-Chek Mobile is a blood glucose monitoring system designed for glucose self-measurements performed by persons with diabetes. The meter and test cassettes are produced by Roche Diagnostics GmbH and are already launched in Scandinavia. The Accu-Chek Mobile system was evaluated by SKUP in 2009. Later Roche has modified the test chemistry to prevent maltose interference. The end-users were not involved in the present SKUP evaluation, and the user-friendliness was not assessed.

The aim of the evaluation
- assess the analytical quality under standardised and optimal conditions, achieved by a biomedical laboratory scientist in a hospital environment
- examine the variation between three lots of test cassettes

Materials and methods
Capillary samples from 81 persons with diabetes and 9 persons without diabetes were collected. The sampling was carried out at Haraldsplass Diaconal Hospital. For each person two measurements on Accu-Chek Mobile were carried out, and a capillary sample was directly prepared for the comparison method. Three lots of test cassettes were used. The quality goal for imprecision was a repeatability CV ≤5%. The quality goal for accuracy was set according to ISO 15197:2003. The quality goal states that 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 and within ±20% at glucose concentrations ≥4,2 mmol/L.

Results
- For glucose level >10 mmol/L the repeatability CV was 3,0%. For glucose levels <7 mmol/L and 7—10 mmol/L the repeatability CV was 4,1% and 4,2%, respectively.
- No bias was present at the three levels of glucose concentration, and 98% of the results were within the accuracy limits.
- One lot of test cassettes showed slightly lower results than the comparison method (−0,4 mmol/L), and one lot showed slightly higher results (+0,3 mmol/L). The third lot showed results in agreement with the comparison method.
- The percentage of technical errors was 1,5%.

Conclusion
The quality goal for imprecision (CV ≤5%), was fulfilled for glucose level >10 mmol/L. For glucose level ≤10 mmol/L the CV was approximately 4%, with the upper CI value >5%. No bias was found. Only small deviations from the comparison method were found with the three lots of test cassettes. The results fulfilled the quality goal for accuracy specified in ISO 15197:2003. The percentage of technical errors fulfilled the goal (≤2%).

Comments from Roche
Roche gratefully accepted the report and had no additional comments.

2. Abbreviations

ADA	American Diabetes Association
BLS	Biomedical Laboratory Scientist
CI	Confidence Interval
C-NPU	Committee on Nomenclature, Properties and Units
CV	Coefficient of Variation
DAK-E	Danish Quality Unit of General Practice
EQA	External Quality Assessment
Equalis	External quality assurance in laboratory medicine in Sweden
HDH	Haraldsplass Diaconal Hospital
HELFO	the Norwegian Health Economics Administration
IFCC	the International Federation of Clinical Chemistry and Laboratory Medicine
ISO	International Organization for Standardization
IUPAC	the International Union of Pure and Applied Chemistry
NIST	National Institute of Standards & Technology
Noklus	Norwegian Quality Improvement of Primary Care Laboratories
PQQ	Pyrroloquinolinquinon
SKUP	Scandinavian evaluation of laboratory equipment for primary health care
SRM	Standard Reference Material

3. Quality goals

3.1 Analytical quality

There are different criteria for setting quality specifications for analytical methods. Ideally the quality goals should be set according to the medical demands the method has to meet. For glucose it is natural that the quality specification is set according to whether the analysis is used for diagnostic purpose or for monitoring diabetes. Accu-Chek Mobile is designed for monitoring blood glucose. The quality goals are set according to this.

Precision
According to the American Diabetes Association (ADA) the imprecision (CV) 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 15197:2003 [5] is an international protocol for evaluating meters designed for glucose monitoring, and gives the following minimum acceptable accuracy requirement:
Ninety-five percent (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 and within ±20% at glucose concentrations ≥4,2 mmol/L.

Quality goals in Denmark
Analytical quality goals for point of care glucose measurement systems: CV <4% and bias <±3% [3,4].

Other analytical quality limits
The number of results within fixed limits of ±15% and ±10% will be reported, but not further assessed in this report.

Variation between lots
The agreement between three lots of test cassettes will be assessed. No specific quality goal for lot variation is set.

Technical errors
SKUP recommends that the percentage of "tests wasted" caused by technical errors should not exceed 2%. The evaluating person registers the number of error codes and technical errors during the evaluation.

3.2 Principles for the assessments

3.2.1 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	The quality goal is fulfilled
The CV is lower than the quality goal (not statistically significant)	Data is inconclusive on fulfilling the quality goal. Most likely the quality goal is fulfilled
The CV is higher than the quality goal (not statistically significant)	Data is inconclusive on fulfilling the quality goal. Most likely the quality goal is not fulfilled
The CV is higher than the quality goal	The quality goal is not fulfilled

Accuracy

The accuracy is illustrated in a difference-plot with limits for the allowable deviation according to the quality goal. The percentage of results within the limits is calculated.
The accuracy is judged as either fulfilling the quality goal or not fulfilling the quality goal.

3.3 SKUP´s quality goals in this evaluation

The results from the evaluation of Accu-Chek Mobile were assessed against the following quality goals as agreed in the protocol:

Repeatability CV …… ≤5%
Allowable deviation in the individual result from the comparison method result (according to ISO 15197:2003)
for glucose concentration <4,2 mmol/L ……≤0,83 mmol/L
for glucose concentration ≥4,2 mmol/L …… ≤±20%
Required percentage of individual results within the allowable deviation …… ≥95%
Percentage of technical errors …… ≤2%

4. Materials and methods

4.1 Definition of the measurand

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and International Union of Pure and Applied Chemistry (IUPAC) work in a joint Committee on Nomenclature, Properties and Units (C-NPU). The descriptions of clinical laboratory tests are listed in the ”NPU database” [6]. In the database the full name is given for the measurand together with which unit the result should be reported in. In this report the term “glucose” will be used for the measurand. Glucose concentrations will be given in mmol/L.

4.2 The evaluated measurement system, Accu-Chek Mobile

Accu-Chek Mobile is a blood glucose monitoring system based on reflectometrical technology. The system consists of an Accu-Chek Mobile meter and a test cassette containing a film with 50 test areas for measurement of glucose (figure 1). A lancet pen is attached to the meter. The system is designed for capillary blood glucose testing performed by persons with diabetes. The system is not recommended in use by health care professionals because of danger of infection from patient to patient. Accu-Chek Mobile reports plasma glucose values. The system is automatically calibrated when inserting a new test cassette. When opening the tip cover, the meter turns on and a new test area will automatically appear. The system requires a blood volume of 0,3 µL. The measurement starts when sufficient amount of blood is applied to the test area. The result is shown in 5 seconds. According to the manufacturer, it is possible to use blood samples from alternative sites. The meter has the capacity of storing 2000 test results in the memory.

Figure 1. Accu-Chek Mobile meter and test cassette

Test principle of Accu-Chek Mobile (according to Roche)
The enzyme, a mutant variant of the quino (PQQ)-protein glucose dehydrogenase (Mut./Q-GDH), oxidizes glucose. The enzyme transfers the reduction equivalents to the oxidized form of the mediator. The reduced form of the mediator reduces the indicator and the indicator changes color from yellow to blue. The color field is flashed by a red LED. The reflected light is indicated by the optical system.

A summary of technical data for Accu-Chek Mobile is shown in table 2. For more details, see attachment 2. For name of the manufacturer and suppliers in the Scandinavian countries, see attachment 3. For product information, see attachment 4.

Table 2. Technical data from the manufacturer

Technical data for Accu-Chek Mobile	
Sample material	Fresh capillary blood
Sample volume	0,3 µL
Measuring time	5 seconds
Measuring range	0,6 — 33,3 mmol/L
Tolerated haematocrit range	25 — 55%
Memory capacity	2000 results
Electrical power supply	2 alkaline-manganese or high energy batteries (1,5 V , type AAA, LR 03, AM 4 or micro)

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 a field method.

4.3.1 The selected comparison method in this evaluation

The selected comparison method in this evaluation is the routine method for quantitative determination of glucose in human serum and plasma in the Laboratory at Haraldsplass Diaconal Hospital (HDH) in Bergen. The method is a photometric glucose hexokinase method and is implemented on 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% and shows a reproducibility CV between 1,1 and 2,5% in daily use.

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 [7]. The 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 [8]. The target value is given with an "expanded uncertainty" of 1,5 — 2% (k=2). The controls are used in Noklus's External Quality Assessment (EQA) program.

4.4 The evaluation

4.4.1 Planning of the evaluation

Background for the evaluation
Accu-Chek Mobile is a blood glucose monitoring system designed for glucose self-measurements performed by persons with diabetes. The Accu-Chek Mobile system is produced by Roche Diagnostics GmbH and supplied in Scandinavia by Roche Diagnostics Scandinavia. Accu-Chek Mobile is already launched in Scandinavia. The Accu-Chek Mobile system was evaluated by SKUP in a user-evaluation in 2009 (SKUP/2009/74) [9]. Later Roche has modified the test chemistry to prevent maltose interference. This change does not affect the handling of the instrument, thus there was no need to involve the end-users or to evaluate the user-friendliness in the present SKUP evaluation. Roche Diagnostics Scandinavia ordered this new evaluation to get objective documentation of the optimal analytical quality of the test cassette in combination with the Accu-Chek Mobile meter, as part of documentation required in the Swedish tender system.

Inquiry about an evaluation
Malin Lundgren, Roche Diagnostics Scandinavia, applied to SKUP in April 2012 for an evaluation of Accu-Chek Mobile glucose meter with Accu-Chek Mobile test cassettes.

Protocol, contract and agreement
The protocol for the evaluation was approved in January 2013. Roche Diagnostics Scandinavia and SKUP signed a contract about the evaluation in January 2013. The laboratory at HDH agreed to analyse the samples for the comparison method.

Preparations, training program and practical work
SKUP started the preparations for the evaluation in December 2012. Marianne Risa, biomedical laboratory scientist (BLS), was familiar with the Accu-Chek system, and further training from Roche was not necessary. The meters and test cassettes for the evaluation were received in January and February 2013. The practical work with the evaluation was carried out during six weeks in the period February - April 2013.

4.4.2 Evaluation sites and persons involved

Persons responsible for the evaluation are shown in table 3.

Table 3. Persons responsible for various parts of the evaluation

Name	Title	Place	Responsibility
Malin Lundgren	Jr Product Manager	Roche Diagnostics Scandinavia	Ordered the evaluation/ Contact person
Grete Monsen	Organisation Secretary	SKUP/Noklus	Responsible for the evaluation
Marianne Risa	BLS	SKUP/Noklus	Preparations for the evaluation Practical work with the evaluation Statistical calculations Author of the report
Grethe Kalleklev and Henriette Mohn Soldal	BLS	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*" [10]. SKUP's model for glucose user-evaluation is based on a standard model used by The Norwegian Health Economics Administration (HELFO) for test strip reimbursement in Norway [11].

The evaluation of Accu-Chek Mobile

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

- An examination of the analytical quality under standardised and optimal conditions, performed by a biomedical laboratory scientist in a hospital environment
    - Precision
    - Accuracy according to the quality goal given in ISO 15197:2003
- An examination of the variation between three lots of test cassettes

4.4.4 Evaluation procedure in a hospital environment

Internal analytical quality control

The BLS used one separate Accu-Chek Mobile meter for each person in the evaluation. The Accu-Chek Mobile meters were checked by means of the manufacturer's control solution the day they were used.

Blood sampling

Capillary samples from 81 persons with diabetes and 9 persons without diabetes were collected. The sampling of the persons with diabetes was carried out in an outpatient clinic and in two hospital wards at HDH. Two measurements on Accu-Chek Mobile were carried out for all the 90 persons, and a capillary sample was directly prepared for the comparison method. The two blood samples for the measurements on Accu-Chek Mobile were collected from the same finger prick. The first drop of blood was wiped off before the first measurement. Blood was also wiped off between the measurements. If necessary a new finger prick was made for the sample for the comparison method. Three different lots of test cassettes were used.

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 into suitable sample vials. 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 [7]).
The samples were analysed during three days in April 2013.

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

5. Results and discussions

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

5.1 Number of samples

Capillary samples from 90 individuals were included in the evaluation.
The total number of samples was:
90 capillary samples x 2 (duplicate measurements on Accu-Chek Mobile)
90 capillary samples x 1 (for the comparison method), analysed in duplicate

5.1.1 Excluded results

The following result is excluded:

- ID 21 was excluded as an outlier according to Burnett's model [12] in the calculation of repeatability on Accu-Chek Mobile and was removed before calculation of trueness and lot variation

5.1.2 Failed measurements

A total of 270 measurements (180 patient samples and 90 control measurements) were performed on the Accu-Chek Mobile meters. Four of these measurements failed; error code E4.
Percentage of technical errors was: (4/270) x 100 = 1,5%

Comments
Error code description from the user's manual:
E4 The test area has absorbed too little blood or control solution.
You did not apply the blood drop or the control solution to the center of the test area.

Discussion
The percentage of technical errors was 1,5% and the goal (≤2%) was fulfilled.

5.2 Analytical quality of the selected comparison method

5.2.1 Internal quality control

In the 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 results are not shown.

5.2.2 The precision of the comparison method

Repeatability

The samples for the comparison method were analysed in duplicate, and the imprecision was calculated by means of these duplicate results. 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). The repeatability of the comparison method with 90% confidence interval (CI) is shown in table 4. The raw data is shown in attachment 6 (only available for the producer).

Table 4. Repeatability of the comparison method with capillary blood samples in the hospital laboratory

Glucose interval, mmol/L	n	Excluded results	Mean value glucose, mmol/L	CV (90% CI), %
<7	23	0	5,70	0,8 (0,7 — 1,1)
7 – 10	26	0	8,67	1,4 (1,2 — 1,8)
>10	41	0	14,49	1,2 (1,0 — 1,5)

Discussion

The repeatability CV for the comparison method was approximately 1%.

5.2.3 The trueness of the comparison method

In order to demonstrate the trueness of the comparison method, the SRM 965b standards purchased from NIST, were analysed. The agreement between the comparison method and the NIST-standards is shown in table 5.

Table 5. 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	09.04.13	**1,836** (1,809 — 1,863)	5	1,83	−0,1
	11.04.13		5	1,85	0,8
	Total		**10**	**1,84**	**0,3**
Level 2	09.04.13	**4,194** (4,135 — 4,253)	5	4,24	1,0
	11.04.13		5	4,18	−0,4
	Total		**10**	**4,21**	**0,3**
Level 3	09.04.13	**6,575** (6,481 — 6,669)	5	6,55	−0,4
	11.04.13		5	6,55	−0,3
	Total		**10**	**6,55**	**−0,4**
Level 4	09.04.13	**16,35** (16,15 — 16,55)	5	16,34	0,0
	11.04.13		5	16,20	−0,9
	Total		**10**	**16,27**	**−0,5**

To verify the trueness of the comparison method results, human serum controls produced by Noklus, were analysed. The target value for the two controls is given with an "expanded uncertainty" of 1,5 — 2% (k=2). The agreement between the comparison method and target values from the Reference laboratory in Belgium is shown in table 6.

Table 6. 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	09.04.13	**5,71** (5,62 — 5,80)	5	5,70	−0,2
	11.04.13		5	5,75	0,7
	Total		**10**	**5,73**	**0,3**
Noklus 2	09.04.13	**11,94** (11,70 — 12,18)	5	11,97	0,2
	11.04.13		5	12,01	0,6
	Total		**10**	**11,99**	**0,4**

Discussion

Table 6 documents that the comparison method produced true glucose values in the evaluation period.

5.3 Analytical quality of Accu-Chek Mobile in a hospital environment

5.3.1 Internal quality control

The Accu-Chek Mobile meters were checked with the manufacturer's control solution the day the meters were in use. The reproducibility CV was 3,2% (n=90). All results were within the control range printed on the test cassette boxes. Raw data is shown in attachment 7.

5.3.2 Comparison of the 1st and 2nd measurements

Two capillary samples were collected of each person for measurements on Accu-Chek Mobile. For the calculation of imprecision, the results have been checked to meet the imposed condition for using formula 1 in attachment 5. No systematic difference was pointed out between the paired measurements on Accu-Chek Mobile (data not shown).

5.3.3 The precision of Accu-Chek Mobile

Repeatability under standardised and optimal measuring conditions in a hospital environment
The repeatability obtained with capillary blood samples is shown in table 7. The results are sorted and divided into three glucose levels according to the first measurement on Accu-Chek Mobile. Raw data is shown in attachment 8.

Table 7. Repeatability, Accu-Chek Mobile. Results achieved with capillary blood samples

Glucose interval, mmol/L	n	Excluded results	Mean value glucose, mmol/L	CV(90% CI) %
<7	22	0	5,6	4,1 (3,2 — 5,6)
7 – 10	27	0	8,4	4,2 (3,5 — 5,4)
>10	41	1*	14,2	3,0 (2,5 — 3,7)

The given numbers of results (n) are counted before the exclusion of outliers. Mean and CV are calculated after the exclusion of outliers.
* One statistical outlier (ID 21) according to Burnett's model

Discussion, repeatability
For glucose level <7 mmol/L and glucose level 7—10 mmol/L the repeatability CV was 4,1% and 4,2%, respectively. The upper CI value is >5%, and the data is inconclusive on fulfilling the quality goal, but most likely the quality goal is fulfilled. For glucose level >10 mmol/L the repeatability CV was 3,0%, and the quality goal of a CV ≤5% was fulfilled.

5.3.4 The trueness of Accu-Chek Mobile

The mean deviation of Accu-Chek Mobile results from the comparison method results (bias) was calculated from the results achieved by the BLS in a hospital environment. The measurements on Accu-Chek Mobile were performed with three lots of test cassettes. The results are sorted and divided into three glucose levels according to the mean results on the comparison method. The trueness of Accu-Chek Mobile is shown in table 8.

Table 8. Trueness of Accu-Chek Mobile

Glucose level Comparison method, mmol/L	**n**	**Excluded results**	**Comparison method mean glucose, mmol/L**	**Accu-Chek Mobile mean glucose, mmol/L**	**Bias (95% CI), mmol/L**
<7	23	0	5,7	5,7	−0,02 ((−0,17) — (+0,13))
7 — 10	26	0	8,7	8,4	−0,24 ((−0,48) — (0,00))
>10	40	0	14,5	14,2	−0,24 ((−0,57) — (+0,09))

Discussion

No significant bias was pointed out at the three levels of glucose concentrations. Still, the Accu-Chek Mobile results tend to be slightly lower than the results from the comparison method. Overall, the glucose measurements on Accu-Chek Mobile showed glucose results in agreement with the comparison method.

5.3.5 The accuracy of Accu-Chek Mobile

To evaluate the accuracy of the results on Accu-Chek Mobile, the agreement between Accu-Chek Mobile and the comparison method is illustrated in an accuracy plot. The plot shows the deviation of single measurement results on Accu-Chek Mobile from the true value, and gives a picture of both random and systematic errors, reflecting the total measuring error on Accu-Chek Mobile. The accuracy is demonstrated for the first measurements of the duplicate results, only. Three different lots of test cassettes were used. The accuracy of Accu-Chek Mobile, with three lots of test cassettes, is shown in figure 2. The accuracy is summarised in table 9.

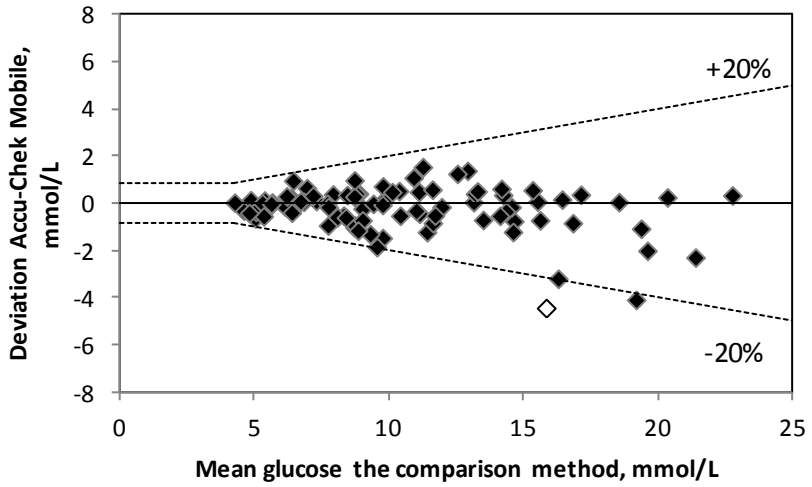

Figure 2. Accuracy. Accu-Chek Mobile with three lots of test cassettes under standardised and optimal measuring conditions. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on Accu-Chek Mobile and the mean value of the duplicate results on 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). ID 21, a statistical outlier in the calculation of repeatability on Accu-Chek Mobile, is shown with an open symbol. Number of results (n) = 90.

Table 9. Accuracy of Accu-Chek Mobile, n= 90

Percentage of results within given limits, %		
ISO 15197:2003	**Fixed limit**	
≤±0,83 mmol/L at conc. <4,2 mmol/L or ≤±20% at conc. ≥4,2 mmol/L	**±15%**	**±10%**
98	96	78

Discussion

Figure 2 shows that the Accu-Chek Mobile glucose results as a whole, tend to be slightly lower than the results from the comparison method. The quality goal in ISO 15197:2003 was fulfilled. Table 9 shows that 98% of the results were within the accuracy quality limits specified in ISO 15197:2003. The number of results within limits of ±15% and ±10% were 96% and 78%, respectively. These results are for information only, and will not be further assessed.

5.3.6 Variation between three lots of test cassettes

The measurements on Accu-Chek Mobile were performed with three lots of test cassettes from different productions. The mean deviation from the comparison method with 95% confidence interval for each of the three lots was calculated as an indirect measure of the lot variation. To get a sufficient number of results in each group, the deviation was calculated for the entire glucose concentration range. The deviation with three lots of test cassettes is shown in table 10.

Table 10. Lotdeviation

Accu-Chek Mobile, lot number of test cassettes	**n**	**Excluded results**	**Comparison method mean, mmol/L**	**Accu-Chek Mobile mean, mmol/L**	**Deviation (95% CI), mmol/L**
491485	29	0	8,9	8,5	−0,38 ((−0,56) — (−0,20))
491502	30	0	11,8	11,5	−0,29 ((−0,60) — (+0,01))
491517	30	1*	10,4	10,7	+0,25 ((+0,01) — (+0,49))

The given numbers of results (n) are counted before the exclusion of outliers. Mean and the deviations are calculated after the exclusion of outliers.
* One statistical outlier (ID 85) according to Burnett's model

Discussion

Only small deviations from the comparison method were pointed out with the three lots of test cassettes. Lot number 491485 showed slightly lower results, and lot number 491517 showed slightly higher results than the comparison method (statistical significant deviations). The small negative deviation of lot number 491502 was not statistically significant. The results from all the three lots fulfil the quality goal in ISO 15197:2003.

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11. www.helfo.no (menu Helsepersonell – Leverandører).
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Attachments

1. The organisation of SKUP
2. Facts about Accu-Chek Mobile
3. Information about manufacturer, retailers and marketing
4. Product information, Accu-Chek Mobile
5. Statistical expressions and calculations
6. Raw data glucose, results from the comparison method
7. Raw data glucose, internal quality control, Accu-Chek Mobile
8. Raw data glucose, Accu-Chek Mobile results under standardised and optimal conditions
9. "SKUP-info". Summary for primary health care (in Norwegian)
10. List of previous SKUP evaluations

Attachment 6 and 8 are included only in the copy to Roche Diagnostics Scandinavia AB.

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 Hillerød 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 Mobile

Parts of this form are filled in by Roche Diagnostics Scandinavia AB.

Table 1. Basic facts

Name of the measurement system:	Accu-Chek Mobile
Dimensions and weight:	Width: 63 mm Depth: 20 mm Height: 121 mm Weight: 129 g
Components of the measurement system:	Accu-Chek Mobile meter, Accu-Chek Fastclix Lancing device, Accu-Chek Fastclix Lancets, Accu-Chek Mobile Tests
Measurand:	Glucose
Sample material:	Capillary blood
Sample volume:	0,3 µl
Measuring principle:	Photometric determination of glucose by means of mutant variant of quinoprotein glucose dehydrogenase (Mut.Q-GDH, EC 1.1.5.2), with colour indicator
Traceability:	Traceable to NIST standard
Calibration:	The system is calibrated with venous blood containing various glucose concentrations. The reference values are obtained using the hexokinase method. The reference method is traceable to a NIST standard using the ID-GCMS method, which is the method of the highest metrological quality.
Measuring range:	0,6 mmol/L to 33,3 mmol/L
Linearity:	0,6 mmol/L to 33,3 mmol/L
Measurement duration:	Approx 5 sec
Operating conditions:	10°C–40°C
Electrical power supply:	2 batteries (type AAA, LR03, AM4 or Micro; 1.5 V)
Recommended regular maintenance:	Moist cloth with water or ethanol 70%
Package contents:	Meter, lancing device, cassette with 50 tests, manual, quick reference guide, USB cable
Necessary equipment not included in the package:	None

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?	Yes
What can be printed?	All stored patient data and control values
Can the instrument be connected to a PC?	Yes
Can the instrument communicate with LIS (Laboratory Information System)? If yes, is the communication bidirectional?	No
What is the storage capacity of the instrument and what is stored in the instrument?	2000 Test results with date, time and flag values
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 Mobile test cassettes
Stability in unopened sealed vial:	18 months
Stability in opened vial:	3 months
Package contents:	50 tests on a cassette

Table 4. Quality control

Electronic self check:	Yes
Recommended control materials and volume:	Accu-Chek Mobile Control /1 application each bottle
Stability in unopened sealed vial:	18 months
Stability in opened vial:	1 application each bottle
Package contents:	2x Control 1, 2x Control 2

Information about manufacturer, retailers and marketing

Table 1. Marketing information

Manufacturer:	Roche Diagnostics
Retailers in Scandinavia:	Denmark: **Roche a/s, Diagnostics** Industriholmen 59, 2650 Hvidovre Phone: +45 36 39 99 54 www.accu-chek.dk Norway: **Roche Diagnostics Norge AS** Brynsengfaret 6B, PB 6610 Etterstad N-0607 Oslo, Norway Phone: +47 23 37 33 00 www.accu-chek.no Sweden: **Roche Diagnostics Sweden** Box 147, 161 26 Bromma, Sweden Phone: +46 8 40488 00 www.accu-chek.se
In which countries is the system marketed:	Globally x Scandinavia ☐ Europe ☐
Date for start of marketing the system in Scandinavia:	Already on the market since March 2009
Date for CE-marking:	Februar 2009
In which Scandinavian languages is the manual available:	All

Product information, Accu-Chek Mobile
SKUP/2013/99*

Accu-Chek Mobile blood glucose meters
A total of 90 Accu-Chek Mobile blood glucose meters were used in this evaluation.

Accu-Chek Mobile test cassettes

Lot 27818542	Expiry 2014-02
Lot 27821144	Expiry 2014-06
Lot 27821541	Expiry 2014-06

Accu-Chek Mobile Control Solution (Control 2)

Lot 66870221	Expiry 2013-12
Target value lot 27818542:	7,8 – 10,5 mmol/L
Target value lot 27821144:	7,8 – 10,5 mmol/L
Target value lot 27821541:	8,0 – 10,8 mmol/L

Blood sampling device (single use only)

Accu-Chek Softclix Pro	
Accu-Chek Softclix Pro Lancets	Lot WIT 44 H 2

Statistical expressions and calculations

This chapter with standardised text deals with the statistical expressions and calculations used by SKUP. The chapter is a short extract of the comprehensive SKUP-document "Statistics in SKUP reports", presented at www.skup.nu, under the option "The SKUP evaluation". The statistical calculations will change according to the type of evaluation. The descriptions in section 4.2 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 field 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
n = number of differences

(formula 1)

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 field method. The mean difference is shown with a 95% confidence interval.

Assessment of accuracy

The agreement between the field 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 field 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*", 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 Mobile

Accu-Chek Mobile Control Solution	Lot-no	Expiry	Lot-no Accu-Chek Mobile test cassettes	Target value Glucose (mmol/L)
Control 2	66870221	2013-12	27818542 (lot a)	7,8 - 10,5
			27821144 (lot b)	7,8 - 10,5
			27821541 (lot c)	8,0 - 10,8

Accu-Chek Mobile Control 2 analysed on the Accu-Chek Mobile meters

ID	Lot-no Accu-Chek Mobile test cassettes	Accu-Chek Mobile Control 2 Glucose (mmol/L)
1	A	9,1
2	A	9,0
3	A	9,4
4	A	9,2
5	A	9,8
6	A	9,5
7	A	9,0
8	A	9,3
9	A	9,2
10	A	9,1
11	A	9,9
12	A	9,1
13	A	8,9
14	A	9,4
15	A	8,9
16	A	9,1
17	A	9,4
18	A	9,0
19	A	9,3
20	A	8,8
21	A	9,2
22	A	9,1
23	A	9,2
24	A	8,8
25	A	9,0
26	A	8,7
27	A	9,3
28	A	9,3
29	A	9,4
30	A	9,3
31	B	9,3
32	B	9,5
33	B	9,8
34	B	9,7
35	B	9,2
36	B	9,3
37	B	9,4
38	B	9,7
39	B	9,2
40	B	9,2
41	B	9,4

ID	Lot-no Accu-Chek Mobile test cassettes	Accu-Chek Mobile Control 2 Glucose (mmol/L)
42	B	9,4
43	B	9,4
44	B	9,4
45	B	9,3
46	B	9,5
47	B	9,7
48	B	9,3
49	B	9,5
50	B	9,7
51	B	10,0
52	B	9,7
53	B	9,3
54	B	9,6
55	B	9,7
56	B	9,4
57	B	9,8
58	B	9,5
59	B	9,5
60	B	9,5
61	C	9,7
62	C	9,8
63	C	9,9
64	C	9,7
65	C	9,9
66	C	9,5
67	C	9,7
68	C	10,1
69	C	9,8
70	C	9,9
71	C	9,7
72	C	9,7
73	C	9,6
74	C	9,5
75	C	9,9
76	C	9,5
77	C	9,5
78	C	9,6
79	C	9,9
80	C	9,5
81	C	9,6
82	C	9,6
83	C	9,7
84	C	9,7
85	C	9,6
86	C	9,7
87	C	9,8
88	C	10,0
89	C	9,8
90	C	9,5

SKUP-info

Accu-Chek Mobile blodsukkerapparat fra Roche Diagnostics
Sammendrag fra en tilleggsutprøving i regi av SKUP

Konklusjon
For glukoseresultater >10 mmol/L var presisjonen på Accu-Chek Mobile god med en CV på 3,0 %. For glukoseresultater <10 mmol/L var presisjonen akseptabel med en CV mellom 4,1 og 4,2 %. Resultatene fra Accu-Chek Mobile samsvarte med resultatene fra sammenligningsmetoden. Et internasjonalt kvalitetsmål fra ISO 15197:2003, med et avvik mindre enn ± 20 % fra en anerkjent glukosemetode, ble oppnådd.

Accu-Chek Mobile er beregnet til egenmåling av blodsukker. Systemet er produsert av Roche Diagnostics GmbH, og består av Accu-Chek Mobile blodsukkerapparat og Accu-Chek Mobile testkassett som inneholder 50 testfelt for måling av glukose. En prøvetakingspenn er festet til apparatet. Apparatet kalibreres automatisk når en ny testkassett settes inn. Det kreves 0,3 µL blod til hver måling. Målingen tar 5 sekunder. Accu-Chek Mobile kan lagre 2000 resultat.

Utprøvingen
Accu-Chek Mobile ble prøvd ut av SKUP i 2009 (SKUP/2009/74). Senere har Roche modifisert testkassettens kjemi for å hindre maltoseinterferens. Tilleggsutprøvingen av Accu-Chek Mobile ble utført under optimale betingelser av laboratorieutdannet personale. Tre ulike lot av testkassetter ble benyttet. Glukoseresultatene fra Accu-Chek Mobile ble sammenlignet med resultatene fra en anerkjent sykehusmetode. Det ble tatt prøver av 81 personer med diabetes og av 9 personer uten diabetes.

Resultater
For glukoseresultater >10 mmol/L var presisjonen på Accu-Chek Mobile god med en CV på 3,0 %. For glukoseresultater <10 mmol/L var presisjonen akseptabel med en CV mellom 4,1 og 4,2 %. Resultatene fra Accu-Chek Mobile samsvarte med resultatene fra sammenligningsmetoden. Kvalitetsmålet fra ISO 15197:2003, som tillater avvik opp til ± 20 % fra en anerkjent metode for måling av glukose, ble oppnådd.

Tilleggsinformasjon
En fullstendig rapport fra utprøvingen av Accu-Chek Mobile, SKUP/2013/99*, 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.

Recent SKUP evaluations

Evaluation no.	Component	Instrument/testkit	Producer
SKUP/2013/99*	Glucose	Accu-Chek Mobile	Roche Diagnostics
SKUP/2013/98*	Glucose	Accu-Chek Aviva	Roche Diagnostics
SKUP/2013/96	Haemoglobin	DiaSpect Hemoglobin T	DiaSpect Medical GmbH
SKUP/2012/95	Glucose[1]	Mendor Discreet	Mendor Oy
SKUP/2012/94	Glucose[1]	Contour XT	Bayer HealthCare
SKUP/2011/93*	Glucose	Accu-Chek Performa	Roche Diagnostics
SKUP/2012/91	HbA1c	Quo-Test A1c	Quoient Diagnostics Ltd
SKUP/2011/90	CRP	*i*-Chroma	BodiTech Med. Inc.
SKUP/2010/89*	Glucose	FreeStyle Lite	Abbott Laboratories
SKUP/2010/88*	HbA1c	*Confidential*	
SKUP/2011/86	Glucose[1]	OneTouch Verio	LifeScan, Johnson & Johnson
SKUP/2013/85	Glucose	StatStrip	Nova Biomedical
SKUP/2011/84*	PT-INR	Simple Simon PT and MixxoCap	Zafena AB
SKUP/2010/83*	Glucose	*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/2010/80	PT (INR)	INRatio2	Alere Inc.
SKUP/2010/79*	Glucose, protein, blood, leukocytes, nitrite	CombiScreen 5SYS Plus urine test strip and CombiScan 100 urine analyser	Analyticon Biotechnologies AG
SKUP/2010/78	HbA1c	In2it	Bio-Rad
SKUP/2011/77	CRP	*Confidential*	
SKUP/2009/76*	HbA1c	*Confidential*	
SKUP/2009/75	Glucose	Contour	Bayer HealthCare
SKUP/2009/74	Glucose[1]	Accu-Chek Mobile	Roche Diagnostics
SKUP/2010/73	Leukocytes	HemoCue WBC	HemoCue AB
SKUP/2008/72	Glucose[1]	*Confidential*	
SKUP/2009/71	Glucose[1]	GlucoMen LX	A. Menarini Diagnostics
SKUP/2011/70*	CRP	smartCRP system	Eurolyser Diagnostica GmbH
SKUP/2008/69*	Strep A	Diaquick Strep A test	Dialab GmbH
SKUP/2013/68	Allergens	ImmunoCap Rapid	Phadia AB
SKUP/2010/67	Allergens	*Confidential*	
SKUP/2008/66	Glucose[1]	DANA DiabeCare IISG	SOOIL Developement co. Ltd
SKUP/2008/65	HbA1c	Afinion HbA1c	Axis-Shield PoC AS
SKUP/2007/64	Glucose[1]	FreeStyle Lite	Abbott Laboratories
SKUP/2007/63	Glucose[1]	*Confidential*	
SKUP/2007/62*	Strep A	QuikRead	Orion Diagnostica Oy
SKUP/2008/61	CRP	i-CHROMA	BodiTech Med. Inc.
SKUP/2007/60	Glucose[1]	*Confidential*	
SKUP/2007/59	Glucose[1]	Ascensia BREEZE2	Bayer HealthCare

*A report code followed by an asterisk indicates evaluations at special request from the supplier, or evaluations that are not complete according to SKUP guidelines, e.g. the part performed by the intended users was not included in the protocol.

[1] Including a user-evaluation among diabetes patients