Accu-Chek Performa

Meter and test strips
designed for glucose self-measurement
and measurements by health care professionals
Manufactured by Roche Diagnostics GmbH

Report from an evaluation
organised by

SKUP

The evaluation was ordered by Roche Diagnostics Sweden AB

SKUP/2011/93*

SKUP in Norway, NOKLUS, Box 6165, NO-5892 Bergen. Phone +47 55 97 95 02. www.SKUP.nu

The report was written by SKUP, October 2011.
Main author was Marianne Risa, SKUP in Norway.

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. 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 as an organisation has no responsibility for www.skup.dk.

[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

To make contact with SKUP

SKUP secretariat
Grete Monsen
+47 55 97 95 02
grete.monsen@noklus.no

SKUP in Denmark
Esther Jensen
Stine Beenfeldt Weber
Hillerød Hospital
Klinisk Biokemisk Afdeling
Dyrehavevej 29, indgang 16A
DK-3400 Hillerød
+45 48 29 41 76
esj@hih.regionh.dk
sbwe@hih.regionh.dk

SKUP in Norway
Grete Monsen
Camilla Eide Jacobsen
Marianne Risa
Sverre Sandberg
NOKLUS
Boks 6165
NO-5892 Bergen
+47 55 97 95 02
grete.monsen@noklus.no
camilla.jacobsen@noklus.no
marianne.risa@noklus.no
sverre.sandberg@isf.uib.no

SKUP in Sweden
Arne Mårtensson
Lena Morgan
Gunnar Nordin
EQUALIS
Box 977
SE-751 09 Uppsala
+46 18 69 31 64
arne.martensson@equalis.se
lena.morgan@equalis.se
gunnar.nordin@equalis.se

www.SKUP.nu

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A detailed list of previous SKUP evaluations is included in the attachments.
Attachments with raw data are included only in the copy to Roche Diagnostics Sweden AB.

1. Summary

Background for the evaluation
Accu-Chek Performa is a blood glucose monitoring system designed for blood testing performed by health care professionals as well as by persons with diabetes. The system is produced by Roche Diagnostics GmbH and is already launched in Scandinavia. The Accu-Chek Performa test strip is almost identical with the test strip evaluated in SKUP/2005/44. Roche in Sweden ordered this new evaluation as part of necessary documentation required in a Swedish tender system. There was no need to involve the end users in the present SKUP evaluation.

The aim of the evaluation
The aim of the evaluation of Accu-Chek Performa was to

- assess the analytical quality under standardised and optimal conditions, performed by a biomedical laboratory scientist in a hospital environment
- examine the variation between three lots of test strips
- evaluate the Accu-Chek Performa owner's booklet and the user-friendliness of Accu-Chek Performa (by one biomedical laboratory scientist)

Materials and methods
Capillary samples from 78 persons with diabetes and 12 persons without diabetes were collected. The sampling was carried out at Haraldsplass Diaconal Hospital. For each person two measurements on Accu-Chek Performa were carried out, and a capillary sample was directly prepared for measurement with a selected comparison method. Three lots of test strips were used. The user-friendliness of Accu-Chek Performa was assessed by means of a questionnaire.

Results

- The precision of Accu-Chek Performa was good. The repeatability CV was between 2,9 and 4,1%. The suggested quality goal for precision was obtained
- Accu-Chek Performa showed glucose results in agreement with the comparison method for glucose concentrations <10 mmol/L. For glucose concentrations >10 mmol/L Accu-Chek Performa had a deviation from the comparison method of -0,5 mmol/L
- The assessment of the accuracy showed that Accu-Chek Performa glucose results were within the accepted quality limits according to ISO 15197
- One of the three lots gave glucose results in agreement with the comparison method. For the two other lots the deviation was -0,28 mmol/L and -0,41 mmol/L, respectively
- The user-friendliness and the owner's booklet were assessed as satisfactory by the biomedical laboratory scientist
- Fraction of technical errors was <2%

Conclusion
The precision of Accu-Chek Performa was good. For glucose concentrations above approximately 10 mmol/L, the results on Accu-Chek Performa were systematically lower than the results from the selected comparison method. The bias was -0,5 mmol/L. The results fulfilled the quality goal proposed in ISO 15197. The user-friendliness and the owner's booklet were assessed as satisfactory. The fraction of technical errors was <2%, and the quality goal was fulfilled.

Comments from Roche
A letter with comments from Roche is attached to the report.

2. Abbreviations

ADA	American Diabetes Association
CI	Confidence Interval
C-NPU	Committee on Nomenclature, Properties and Units
CV	Coefficient of Variation
DAK-E	Danish Quality Unit of General Practice
EQUALIS	External quality assurance in laboratory medicine in Sweden
HDH	Haraldsplass Diaconal Hospital
IFCC	the International Federation of Clinical Chemistry and Laboratory Medicine
IUPAC	the International Union of Pure and Applied Chemistry
NOKLUS	Norwegian Quality Improvement of Primary Care Laboratories
SD	Standard Deviation
SKUP	Scandinavian evaluation of laboratory equipment for primary health care

3. Quality goals

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

3.1 Analytical quality goals

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 Performa is designed for monitoring blood glucose, and it is reasonable to set the quality goals according to this.

Precision
For glucose meters designed for monitoring blood glucose one should point out the need of a method with good precision [1]. According to the American Diabetes Association (ADA) the imprecision (CV) of new glucose devices must be less than 5% [2]. Other authors also recommend an imprecision of 5% or less [3].

Accuracy
The quality goal set in ISO 15197, *In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus* [4] applies for glucose measurements performed by health care professionals, and has been used as a quality goal for previous glucose evaluations organised by SKUP [5, 6, 7]. The ISO-guide 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
A committee appointed by the National Ministry of Health in Denmark has specified demands to analytical quality for medical laboratory activities in primary health care. The analytical quality goals for point of care glucose measurement systems in Denmark are CV <4% and bias <3% [8].

3.2 Evaluation of user-friendliness

The evaluation of user-friendliness is carried out by asking the evaluating person to fill in a questionnaire, see section 6.4.

The questionnaire divides the user-friendliness into four sub-areas:

- Rating of the information in the manual and insert
- Rating of time factors for the measurement and preparation
- Rating of performing internal and external quality control
- Rating of operation facilities. Is the system easy to handle?

Evaluation of user-friendliness is graded as satisfactory, intermediate or unsatisfactory, also depicted by the colours green, yellow, and red.
To achieve the overall rating ”satisfactory”, the tested equipment must reach the total rating of “satisfactory” in all four sub-areas of characteristics mentioned above.

The evaluating person registers the fraction of error codes and technical errors during the evaluation. General practitioners in Denmark mean that the fraction of “tests wasted” caused by technical errors should not exceed 2%.

3.3 SKUP´s quality goals in this evaluation

Based on the discussion about analytical quality goals above, it was agreed to assess the results from the evaluation of Accu-Chek Performa against the following quality goals:

Repeatability CV	<5%
Accuracy according to ISO 15197	<±20%
Fraction 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 the 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” [9]. In the database, the recommended name is given for the measurand, together with which unit the result should be reported.

Table 1. Name, code and unit for P — Glucose tests according to C-NPU

NPU code	Full name of test according to NPU	Short name	Unit
NPU22089	Plasma (capillary Blood) — Glucose; substance concentration = ?	P(cB) — Glucose	mmol/L

In this report the term glucose will be used for the measurand.

4.2 The evaluated measurement system

4.2.1 Description of Accu-Chek Performa

Accu-Chek Performa is a blood glucose monitoring system based on electrochemical biosensor technology. The system consists of the Accu-Chek Performa meter and dry reagent test strips. The system is designed for blood glucose testing performed by persons with diabetes or by health care professionals. Fresh, whole blood is required to perform a blood glucose test. According to the information in the owner’s booklet, fresh capillary, venous, arterial or neonatal whole blood may be used. Accu-Chek Performa reports plasma glucose values. The system requires calibration by the user (snap-in code chip). The user has to make sure that the code number displayed by the meter when the meter is activated matches the code number printed on the test strip box. The test strips are packed in a plastic bottle with flip-top closure and desiccant. The system requires a blood volume of 0,6 µL. The blood is automatically drawn into the test strip. The result is shown in 5 seconds. According to the owner’s booklet, it is possible to use blood samples from alternative sites as the forearm, upper arm, thigh or lower leg on Accu-Chek Performa. The meter has the capacity of storing 20 control results and 500 test results in the memory. For more information about Accu-Chek Performa, see table 2 and attachment 1.

Test principle of Accu-Chek Performa
Glucose dehydrogenase converts glucose to gluconolactone. The cofactor in the reaction is modified pyrroloquinolinquinon (PQQ). The cofactor is modified to prevent maltose-interference.

$$\text{Glucose} + \text{Mediator}_{\text{Oxidized}} \xrightarrow{\text{PQQ Glukose Dehydrogenase}} \text{Gluconolactone} + \text{Mediator}_{\text{Reduced}}$$

4.2.2 Product information, Accu-Chek Performa

Accu-Chek Performa is manufactured by Roche Diagnostics GmbH. Technical data from the manufacturer is shown in table 2. For names of suppliers in the Scandinavian countries and more details about Accu-Chek Performa, see attachment 1.

Table 2. Technical data from the manufacturer

TECHNICAL DATA FOR ACCU-CHEK PERFORMA	
Optimal operating temperature	8 – 44 °C
Humidity	10 – 90%
Sample material	Fresh whole blood (capillary, venous, arterial or neonatal whole blood)
Sample volume	0,6 µL
Measuring time	5 seconds
Measuring range	0,6 – 33,3 mmol/L
Hematocrit	Not affected by hematocrit values from 10 to 65 %
Storage capacity	20 control results and 500 test results
Electrical power source	One 3-volt lithium battery (type 2032)
Operating time	Approximately 500 tests
Dimensions	93 mm x 52 mm x 22 mm
Weight	Approximately 62 g (including the battery)

Accu-Chek Performa serial number
Accu-Chek Performa with serial number 55204055678 was used throughout the evaluation.

Accu-Chek Performa test strips
Lot 470260 Expiry 2012-08-31
Lot 470190 Expiry 2012-07-31
Lot 470220 Expiry 2012-07-31

Accu-Chek Performa Control
The Accu-Chek Performa Control is a blue aqueous glucose solution produced with glucose concentrations in low and high range. Both controls were used in this evaluation.

Lot 10100323 Expiry 2013-01-31

Target value Control 1: 1,7 – 3,3 mmol/L
Control 2: 14,5 – 19,6 mmol/L

4.3 The selected comparison method

The selected comparison method is a fully specified method which, in the absence of a Reference method, serves as the common basis for the comparison of a field method. In a SKUP evaluation the selected comparison method is usually a well established routine method in a hospital laboratory. The trueness of the comparison method is usually documented with reference materials and/or by comparison with external quality controls from an external quality assurance programme. A glucose comparison method should be a plasma method, hexokinase by preference.

4.3.1 The selected comparison method in this evaluation

In this evaluation, the routine method for quantitative determination of glucose in human serum and plasma (e.g. lithium heparin) in the Laboratory at Haraldsplass Diaconal Hospital (HDH) was used as the selected comparison method. The comparison method is a photometric enzymatic method, utilising hexokinase and glucose-6-phosphate dehydrogenase enzymes. The method is implemented on Architect *ci*8200 System from Abbott Laboratories, with reagents and calibrators from Abbott Laboratories. The measuring principle is as follows: Glucose is phosphorylated by hexokinase in the presence of ATP and magnesium ions. The glucose-6-phosphate that is formed is oxidised in the presence of glucose-6-phosphate dehydrogenase causing the reduction of NAD to NADH. The produced NADH absorbs light at 340 nm and is detected spectrophotometrically as an increased absorbance.

4.3.2 Verifying of the analytical quality of the comparison method

The comparison method has to show traceability equivalent to that of an internationally accepted reference solution, such as the standards supplied by the National Institute of Standards & Technology, NIST. The NIST-standard SRM 965b [10] consists of ampoules with human serum with certified concentrations of glucose at four levels, with given uncertainties. The uncertainty is defined as an interval estimated to have a level of confidence of at least 95%. The SRM 965b materials cover a glucose concentration range from 1,8 to 16,4 mmol/L, and were used in this evaluation to verify the trueness. In addition, freshly frozen, human serum controls, produced by SERO AS, 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; Laboratory for Analytical Chemistry, University of Gent, Belgium [11]. The controls are used in NOKLUS's External Quality Assessment program. The results are summarized in chapter 6.2.3.

Internal quality assurance of the comparison method during the evaluation period
Autonorm Human Liquid Control Solutions at two levels from SERO AS were included in the measuring series in this evaluation.

4.3.3 Product information, the comparison method

Comparison method on Architect ci8200
Architect ci8200 is manufactured by Abbott Laboratories.
Serial no. C800890

Glucose reagent
Lot 40525UQ11 Expiry 2011-11-30

Calibrator
Multiconstituent Calibrator
Lot 83811M500 Expiry 2011-10-31 Reference value, cal 1 = 5,27 mmol/L
Reference value, cal 2 = 24,53 mmol/L

Internal quality controls
Autonorm Human Liquid 1 and 2, SERO AS
Liquid 1: Value = 3,198 ± 0,10 mmol/L Lot 1005292 Expiry 2012-07
Liquid 2: Value = 15,63 ± 0,39 mmol/L Lot 1008490 Expiry 2012-10

Quality controls produced by SERO AS
Reference value from Laboratory for Analytical Chemistry, University of Gent, Belgium; ID-GCMS method
Serum TM Gluc L-1 Value = 4,78 ±0,09 mmol/L Lot 0809361 Expiry 2010-06*
Serum TM Gluc L-2 Value = 11,80 ±0,16 mmol/L Lot 0809362 Expiry 2010-06*
* The stability of the controls was documented again in October 2010 and the expiration date has been extended.

NIST standards
Standard Reference Material® 965b, National Institute of Standards & Technology
Expiry 2014-12-31
Level 1: Value = 1,836 ±0,027 mmol/L
Level 2: Value = 4,194 ±0,059 mmol/L
Level 3: Value = 6,575 ±0,094 mmol/L
Level 4: Value = 16,35 ±0,20 mmol/L

Blood sampling device
Accu-Chek Softclix Pro
Accu-Chek Softclix Pro lancets Lot WIT 44 H 2 Expiry 2011-10-31

Tubes used for sampling for the comparison method
Microvette CB 300 LH (lithium-heparin) manufactured by Sarstedt AS
Lot 1071701 Expiry 2014-04

Centrifuge
Eppendorf MiniSpin Serial no. 0022772

4.4 Planning of the evaluation

Background for the evaluation
Accu-Chek Performa is a blood glucose monitoring system designed for blood testing performed by health care professionals as well as by persons with diabetes. The Accu-Chek Performa system is produced by Roche Diagnostics GmbH and supplied in Scandinavia by Roche. Accu-Chek Performa is already launched in Scandinavia. The Accu-Chek Performa test strip is almost identical with the test strip already evaluated in a previous user-evaluation (SKUP/2005/44). Therefore there was no need to involve the end users in the present SKUP evaluation. Roche in Sweden ordered this new evaluation to get objective documentation of the optimal analytical quality of the test strip in combination with the Accu-Chek Performa meter, as part of necessary documentation required in a Swedish tender system.

Inquiry about an evaluation
Mette Engebretsen, Roche Diagnostics Norge AS, on behalf of Roche in Sweden, applied to SKUP in March 2011 for an evaluation of Accu-Chek Performa glucose meter with Accu-Chek Performa test strips. SKUP accepted to carry out this evaluation.

Protocol, agreements and contract
The protocol for the evaluation was approved in June 2011. Roche Diagnostics Sweden AB and SKUP signed a contract about the evaluation in July 2011. The laboratory at Haraldsplass Diaconal Hospital in Bergen agreed to carry out the analytical part of the evaluation centred around analysing the samples for the comparison method.

Preparations, training program and practical work
SKUP started the preparations for the evaluation in April 2011. Marianne Risa was familiar with the Accu-Chek system from previous glucose evaluations, and further training from Roche was not necessary. The meters and test strips for the evaluation were received in May 2011. The practical work with the evaluation was carried out during six weeks in the period from June to August 2011.

4.4.1 Evaluation sites and persons involved

The evaluation took place at Haraldsplass Diaconal Hospital (HDH) in Bergen, Norway. The blood sampling and the measurements on Accu-Chek Performa, were carried out by Marianne Risa, biomedical laboratory scientist, SKUP/NOKLUS. Henriette Mohn Soldal and Grethe Kalleklev, biomedical laboratory scientists at the Laboratory at HDH, were given the responsibility for the practical work with the comparison method. Marianne Risa, SKUP/NOKLUS did the statistical calculations and report writing.

4.5 The evaluation procedure

4.5.1 The evaluation model

The SKUP evaluation
SKUP evaluations are based upon the fundamental guidelines in the book "*Evaluation of analytical instruments. A guide particularly designed for evaluations of instruments in primary health care*" [12]. In principle, an evaluation of a self-monitoring blood glucose device follows the guidelines in the book, but the evaluation in primary health care is replaced by a user-evaluation conducted among persons with diabetes, based on the model worked out by the NOKLUS-project "*Diabetes-Self-measurements*" [13]. The Accu-Chek Performa test strip is more or less identical with the test strip already evaluated in a previous user-evaluation (SKUP/2005/44). Roche in Sweden ordered this new evaluation to get objective documentation of the optimal analytical quality of the Accu-Chek Performa test strip in combination with the Accu-Chek Performa meter. There was no need of involving the end users in the present SKUP evaluation.

The evaluation of Accu-Chek Performa 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 ISO 15197
- An examination of the variation between three lots of test strips
- An examination of the user-friendliness of Accu-Chek Performa
- An evaluation of the owner's booklet of Accu-Chek Performa

4.5.2 Evaluation procedure in a hospital environment

Training
Marianne Risa was familiar with the Accu-Chek system from previous glucose evaluations. Further training from Roche was not necessary.

Internal analytical quality control
The Accu-Chek Performa meter was checked by means of the manufacturer's control solutions every day it was used.

Blood sampling
Capillary samples from 78 persons with diabetes and 12 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 Haraldsplass Diaconal Hospital. Two measurements on Accu-Chek Performa were carried out for all the 90 persons, and a capillary sample was directly prepared for measurement on the comparison method. Three different lots of test strips were used. The samples for Accu-Chek Performa, as well as the samples for the comparison method, were collected from finger capillaries. The sampling sequence was started with duplicate measurements on Accu-Chek Performa, immediately followed by a sample for the comparison method. The blood sample for the duplicate measurements was 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 duplicates. If necessary a new finger prick was made for the sample for the comparison method.

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 10.000g, 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 [10].

The samples were thawed at NOKLUS just before they were analysed on the comparison method. The samples were analysed during four days in August 2011.

Evaluation of user-friendliness and owner's booklet
The evaluation of user-friendliness was carried out by filling in a questionnaire, see section 6.4.

5. 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 section 5.2 are valid for evaluations of quantitative methods with results on the ratio scale.

5.1 Statistical terms and expressions

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

5.1.1 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, intermediate, 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.

5.1.2 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, intermediate, poor e.g.), whereas the bias is reported in the same unit as the analytical result or in percent.

5.1.3 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, intermediate, 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

5.2 Statistical calculations

5.2.1 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.

5.2.2 Calculations of imprecision based on duplicate results

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 (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 assumption for using the formulas is that there is no systematic difference between the 1st and the 2nd measurement of the pairs.

5.2.3 Calculation of bias (trueness)

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.

5.2.4 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

6. Results and discussions

6.1 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 the biomedical laboratory scientist's meter)
90 capillary samples x 1 (for the comparison method), analysed in duplicate

6.1.1 Excluded results

The following result is excluded:

- ID 9 was classified as an outlier according to Burnett's model in the calculation of repeatability on the comparison method. These results are excluded, and the matching meter results removed before assessment of accuracy and before calculation of trueness and lot variation

6.1.2 Failed measurements

Measurement with one test strip failed due to error E1 (damaged test strip).

6.2 Analytical quality of the selected comparison method

6.2.1 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. The control results in the evaluation period (four days) were inside the limits of the target values for the controls. The results are not shown.

6.2.2 The precision of the comparison method

Repeatability

The best estimate of the repeatability of a method is achieved by using patient samples. By doing so, matrix effects in artificially produced materials are avoided. The samples for the comparison method were analysed in duplicate, and the imprecision was calculated by means of these duplicate results. The results have been checked to meet the assumption in 5.2.2. No systematic difference was pointed out (results not shown). The SD was approximately similar for the three glucose concentration intervals and formula 1 (in section 5.2.2) was used for the calculation of repeatability. The repeatability of the comparison method is shown in table 3. The raw data is shown in attachment 2.

Table 3. Repeatability of the comparison method with capillary blood samples in the hospital laboratory

Level	Comparison method interval (10^9/L)	n	Excluded results	Comparison method, mean (mmol/L)	CV% (95% CI)
Low	<7	28	0	5,6	1,2 (0,9 — 1,6)
Medium	7 — 10	24	1*	8,7	1,3 (1,0 — 1,8)
High	>10	38	0	14,5	1,0 (0,8 — 1,3)

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 9) according to Burnett's model

Discussion

The precision of the comparison method was good. The repeatability CV was approximately 1% and equivalent to results achieved in previous corresponding evaluations.

6.2.3 The trueness of the comparison method

In order to demonstrate the trueness of the comparison method, the SRM 965b standards supplied by NIST, were analysed. The agreement between the comparison method and the NIST-standards is shown in table 4.

Table 4. Standard Reference Material (SRM 965b) measured on the comparison method

SRM 965b	Date	Certified glucose concentration mmol/L (uncertainty)	n	Mean value glucose (mmol/L)	% deviation from target value
Level 1	23.08.2011	**1,836** (1,809 — 1,863)	5	1,90	3,4
	31.08.2011		5	1,84	0,0
	Total		**10**	**1,87**	**1,7**
Level 2	23.08.2011	**4,194** (4,135 — 4,253)	5	4,38	4,5
	31.08.2011		5	4,28	2,0
	Total		**10**	**4,33**	**3,2**
Level 3	23.08.2011	**6,575** (6,481 — 6,669)	5	6,83	3,8
	31.08.2011		5	6,62	0,7
	Total		**10**	**6,73**	**2,3**
Level 4	23.08.2011	**16,35** (16,15 — 16,55)	5	17,31	5,9
	31.08.2011		5	16,75	2,4
	Total		**10**	**17,03**	**4,2**

Comments

The samples for the comparison method were analysed during four days. The first 45 samples were analysed on the 23rd and the 24th of August. The last 45 samples were analysed on the 30th and the 31st of August. Table 4 shows that the glucose results of the NIST-standards on the comparison method were higher than the certified glucose concentration. On the 23rd of August the deviation from the target value was from 3,4 to 5,9%. The comparison method was recalibrated the 29th of August. All results from Architect are adjusted according to the certified NIST-targets. The adjustment was carried out by means of inverse calibration [14, 15].

The samples analysed before the recalibration (ID 1 to ID 45), are adjusted by the regression equation: $y = 0,9407x + 0,0844$.

The samples analysed after the recalibration (ID 46 to ID 90), are adjusted by the regression equation: $y = 0,973x + 0,0664$.

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

To verify the trueness of the comparison method, freshly frozen, human serum controls with glucose concentrations at two levels were analysed. The agreement between the comparison method and target values from the Reference laboratory in Belgium is shown in table 5.

Table 5. Trueness of the comparison method

Control	Date	Target value glucose (mmol/L)	n	Mean value glucose (mmol/L)	% deviation from target value
TM Gluc L-1	23.08.2011	4,78	5	4,76	-0,5
	31.08.2011		5	4,78	0,0
	Total		**10**	**4,77**	**-0,3**
TM Gluc L-2	23.08.2011	11,80	5	11,75	-0,5
	31.08.2011		5	11,75	-0,5
	Total		**10**	**11,75**	**-0,5**

Discussion

The trueness of the comparison method was good.

6.3 Analytical quality of Accu-Chek Performa in a hospital environment

6.3.1 Internal quality control

The Accu-Chek Performa meter was checked with the manufacturer's control solutions every day the meter was in use. All results were within the control range printed on the test strip box.

6.3.2 Comparison of the 1st and 2nd measurements

Two capillary samples were taken of each person for measurements on Accu-Chek Performa. The results have been checked to meet the assumption in 5.2.2. Table 6 shows that for two of the three concentration levels no systematic difference was pointed out. The difference for low glucose concentrations is slightly significant, but may have appeared by chance. For the total set of data the conclusion is that there is no systematic difference between the paired measurements. This conclusion is also supported by observations in previous evaluations carried out by SKUP.

Table 6. Comparison of the 1st and 2nd measurement on Performa. T-test for paired values

Accu-Chek Performa Glucose level (mmol/L)	n	Mean glucose 1st measurement (mmol/L)	Mean glucose 2nd measurement (mmol/L)	Mean difference 2nd – 1st measurement (mmol/L)	95% CI for the mean difference (mmol/L)
<7	30	5,4	5,6	0,17	(0,07) — (+0,27)
7 – 10	27	8,6	8,8	0,17	(-0,01) — (+0,35)
≥10	33	14,1	14,0	-0,09	(-0,29) — (+0,11)

6.3.3 The precision of Accu-Chek Performa

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 Performa. The raw data is shown in attachment 3.

Table 7. Repeatability, Accu-Chek Performa. Results achieved with capillary blood samples measured under standardised and optimal conditions

Glucose level (mmol/L)	n	Excluded results	Mean value glucose (mmol/L)	CV% (95% CI)
<7	30	0	5,5	4,1 (3,3 — 5,6)
7 – 10	27	0	8,7	3,9 (3,1 — 5,4)
≥10	33	0	14,0	2,9 (2,3 —3,8)

Reproducibility with Internal Quality Control Solutions
The reproducibility is assessed with the Accu-Chek Performa Controls. Artificially produced control materials have other matrix effects than whole blood, and may give other results than results achieved with blood. The measurements are carried out on the Accu-Chek Performa meter (three different lots of test strips) during the whole evaluation period. The reproducibility of Accu-Chek Performa is shown in table 8. The raw data is shown in attachment 4.

Table 8. Reproducibility. Results achieved with Accu-Chek Performa Control Solutions

Accu-Chek Performa Control	n	Excluded results	Target value glucose (mmol/L)	Mean value glucose (mmol/L)	CV% (95% confidence interval)
Control 1	16	0	1,7 — 3,3	2,6	1,9 (1,4 — 3,0)
Control 2	16	0	14,5 —19,6	17,4	1,7 (1,3 —2,6)

Discussion, repeatability, and reproducibility
The precision obtained under standardised and optimal conditions was good. The repeatability CV was between 2,9 and 4,1%. The recommended quality goal for precision was obtained.
The reproducibility on Accu-Chek Performa under standardised and optimal conditions was good when measured with Accu-Chek Performa Control Solutions. The reproducibility CV was below 2%.

6.3.4 The trueness of Accu-Chek Performa

The trueness of Accu-Chek Performa is calculated from the results achieved by the biomedical laboratory scientist in a hospital environment. The measurements on Accu-Chek Performa were performed with three lots of test strips. The results are sorted and divided into three glucose levels according to the mean results on the comparison method. The results are shown in table 9.

Table 9. Trueness of Accu-Chek Performa

Glucose level Comparison method (mmol/L)		**n**	**Excluded results**	**Comparison method, mean glucose (mmol/L)**	**Accu-Chek Performa, mean glucose (mmol/L)**	**Mean deviation from the Comparison method, mmol/L (95% CI)**
Low	<7	29	0	5,46	5,43	-0,03 ((-0,12) — (+0,06))
Medium	7 - 10	25	1*	8,64	8,53	-0,11 ((-0,30) — (+0,08))
High	>10	36	0	14,18	13,67	-0,51 ((-0,77) — (-0,25))

The given numbers of results (n) are counted before the exclusion of outliers. Mean and CV are calculated after the exclusion of outliers

* ID 9 was classified as an outlier according to Burnett's model in the calculation of repeatability on the comparison method. These results and the matching meter results are excluded before the calculation

Discussion

Accu-Chek Performa showed glucose results in agreement with the comparison method for glucose concentrations <10 mmol/L. For glucose concentrations >10 mmol/L Accu-Chek Performa showed lower glucose results than the comparison method. The deviation from the comparison method was approximately -0,5 mmol/L for glucose concentrations above 10 mmol/L. The deviation was small, but statistically significant.

6.3.5 The accuracy of Accu-Chek Performa

To evaluate the accuracy of the results on Accu-Chek Performa, the agreement between Accu-Chek Performa and the comparison method is illustrated in a difference-plot. The plot shows the deviation of single measurement results on Accu-Chek Performa from the true value, and gives a picture of both random and systematic deviation, reflecting the total measuring error on Accu-Chek Performa. Three different lots of test strips were used. The limits in the plot represent quality limits set in ISO 15197. The accuracy of Accu-Chek Performa, with three lots of test strips, is shown in figure 1.

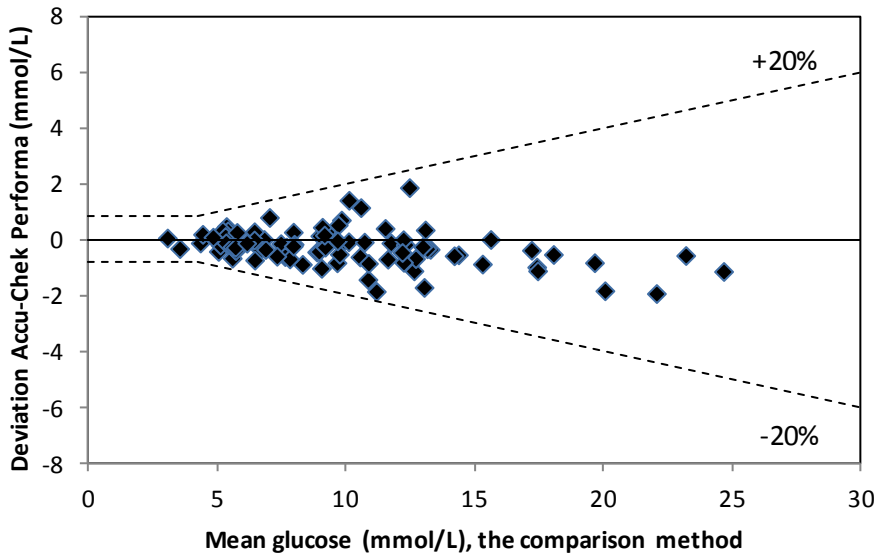

Figure 1. Accuracy. Accu-Chek Performa with three lots of test strips under standardised and optimal measuring conditions. The x-axis represents the mean value of the duplicate results on the comparison method. The y-axis shows the difference between the first measurement on Accu-Chek Performa and the mean value of the duplicate results on the comparison method. Stippled lines represent quality goal limits set in ISO 15197 (±20%). n = 89

Discussion

Figure 1 shows that Accu-Chek Performa glucose results were in agreement with the comparison method for glucose concentrations below approximately 10 mmol/L. For glucose concentrations above approximately 10 mmol/L most of the results on Accu-Chek Performa were lower than the results from the comparison method. All results were inside the accuracy quality limits. The quality goal proposed in ISO 15197 was fulfilled.

6.3.6 Variation between three lots of test strips

The measurements on Accu-Chek Performa were performed with three different lots of test strips. The deviation for each of the three lots from the comparison method was calculated (paired t-test), as an indirect measure of the lot variation. The results were sorted according to the lot of the test strips. To get a sufficient number of results in each group, the deviation of each lot must be calculated for the entire glucose concentration range. The results are shown in table 10.

Table 10. Variation between three lots of test strips

Accu-Chek Performa, lot number of test strips	**n**	**Excluded results**	**Comparison method, mean (mmol/L)**	**Accu-Chek Performa, mean (mmol/L)**	**Mean deviation from the Comparison method, mmol/L (95% CI)**
470260	29	1*	10,3	10,1	-0,28 ((-0,50) — (-0,06))
470190	30	0	9,1	9,1	-0,05 ((-0,27) — (+0,18))
470220	30	0	10,1	9,7	-0,41 ((-0,62) — (-0,20))

The given numbers of results (n) are counted before the exclusion of outliers. Mean and CV are calculated after the exclusion of outliers

* ID 9 was classified as an outlier according to Burnett's model in the calculation of repeatability on the comparison method. These results and the matching meter results are excluded before the calculation

Discussion

Statistically, glucose results on Accu-Chek Performa with two of the three lots of test strips used in this evaluation were significantly lower than the results achieved with the comparison method. The deviation was -0,28 mmol/L for lot 470260 and -0,41 mmol/L for lot 470220. The deviation was small, but statistically significant. Lot 470190 gave glucose results in agreement with the comparison method. The results fulfil the quality goal in ISO 15197.

6.4 Evaluation of user-friendliness

6.4.1 The questionnaire

At the end of the evaluation period, the biomedical laboratory scientist responsible for the practical work filled in a questionnaire about the user-friendliness of the instrument. The questionnaire and the expressed opinions are presented in Table 11 to 14. The first column shows the considerate topics. The second column shows the rating by the user at the evaluation site. The third to fifth column show the rating options. Coloured frames mark the cells with the overall rating from the evaluating site. The last row in each table summarises the rating in the table. The total rating is an overall assessment of the described property, and not necessarily the arithmetic mean of the rating in the row. Consequently, a single poor rating can justify an overall poor rating, if this property seriously influences on the user-friendliness of the system. Unsatisfactory and intermediate ratings will be marked with an asterisk and explained below the table.

Comment

In this evaluation, the user-friendliness was assessed by one biomedical laboratory scientist.

Table 11. Assessment of the information in the manual / insert

Information in manual / insert about:	**Ratings**	**Red**	**Yellow**	**Green**
General impression		Unsatisfactory	Intermediate	Satisfactory
Table of contents		Unsatisfactory	Intermediate	Satisfactory
Preparations / Pre-analytic procedure		Unsatisfactory	Intermediate	Satisfactory
Specimen collection *		Unsatisfactory	Intermediate	Satisfactory
Measurement / Reading		Unsatisfactory	Intermediate	Satisfactory
Measurement principle		Unsatisfactory	Intermediate	Satisfactory
Sources of error		Unsatisfactory	Intermediate	Satisfactory
Fault-tracing / Troubleshooting		Unsatisfactory	Intermediate	Satisfactory
Keyword index		Unsatisfactory	Intermediate	Satisfactory
Readability / Clarity of presentation		Unsatisfactory	Intermediate	Satisfactory
Available insert in Danish, Norwegian, Swedish		Unsatisfactory	Intermediate	Satisfactory
Others comments about information in the manual / insert (please specify)		Unsatisfactory	Intermediate	Satisfactory
Rating for the information in the manual				Satisfactory

Positive comments: —
*Negative comments: The illustration of specimen collection shows puncturing of the first finger. According to different guidelines, puncturing of the middle finger or the ring finger is preferable.

Table 12. Assessment of time factors

Time factors	**Ratings**	**Red**	**Yellow**	**Green**
Time for preparations / Pre-analytical time		>10 min	6 to 10 min.	<6 min.
Analytic time		>20 min	10 to 20 min.	<10 min.
Required training time		>8 hours	2 to 8 hours	<2 hours
Stability of test, unopened package		<3 months	3 to 5 months	>5 months
Stability of test, opened package		<14 days	14 to30 days	>30 days
Other comments about time factors (please specify)		Unsatisfactory	Intermediate	Satisfactory
Rating of time factors				Satisfactory

Positive comments: —
Negative comments: —

Table 13. Assessment of quality control possibilities

Quality Control	**Ratings**	**Red**	**Yellow**	**Green**
Internal quality control		Un-satisfactory	Intermediate	Satisfactory
External quality control		Un-satisfactory	Intermediate	Satisfactory
Stability of quality control material, unopened		<3 months	3 to5 months	>5 months
Stability of quality control material, opened		≤1 day	2 to 6 days	>6 days or disposable
Storage conditions for quality control materials, unopened *		–20°C	+2 to +8°C	+15 to +30°C
Storage conditions for quality control materials, opened		–20°C	+2 to +8°C	+15 to +30°C
Usefulness of the quality control		Unsatisfactory	Intermediate	Satisfactory
Other comments about quality control (please specify)		Unsatisfactory	Intermediate	Satisfactory
Rating of quality control				Satisfactory

*Positive comments: The quality control solutions can be stored at +2 to +32°C.
Negative comments: —

Table 14. Assessment of the operation facilities

Operation facilities	Rating	Red	Yellow	Green
To prepare the test / instrument		Unsatisfactory	Intermediate	Satisfactory
To prepare the sample		Unsatisfactory	Intermediate	Satisfactory
Application of specimen		Unsatisfactory	Intermediate	Satisfactory
Specimen volume		Unsatisfactory	Intermediate	Satisfactory
Number of procedure step		Unsatisfactory	Intermediate	Satisfactory
Instrument / test design		Unsatisfactory	Intermediate	Satisfactory
Reading of the test result		Difficult	Intermediate	Easy
Sources of errors		Unsatisfactory	Intermediate	Satisfactory
Cleaning / Maintenance		Unsatisfactory	Intermediate	Satisfactory
Hygiene, when using the test		Unsatisfactory	Intermediate	Satisfactory
Storage conditions for tests, unopened package*		–20°C	+2 to +8°C	+15 to +30°C
Storage conditions for tests, opened package		–20°C	+2 to +8°C	+15 to +30°C
Environmental aspects: waste handling		Special precautions	Sorted waste	No precautions
Intended users		Biomedical scientists	Laboratory experienced	GP personnel or patients
Size and weight of package		Unsatisfactory	Intermediate	Satisfactory
Other comments about operation facilities (please specify)		Unsatisfactory	Intermediate	Satisfactory
Rating of operation				Satisfactory

*Positive comments: The tests strips can be stored at +2 to +30°C.
Negative comments: —

6.4.2 Assessment of the user-friendliness

The user-friendliness of Accu-Chek Performa was assessed as satisfactory. The person evaluating the system was satisfied with the use of Accu-Chek Performa.

7. References

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Attachments

1. Facts about Accu-Chek Performa
2. Raw data glucose, results from the comparison method
3. Raw data glucose, Accu-Chek Performa results under standardised and optimal conditions
4. Raw data glucose, internal quality control, Accu-Chek Performa
5. "SKUP-info". Summary for primary health care (in Norwegian)
6. List of previous SKUP evaluations
7. Comments from Roche

Attachments with raw data are included only in the report to Roche Diagnostics Sweden AB.

Facts about Accu-Chek Performa

This form is filled in by Roche.

Table 1. Basic facts

Name of the measurement system:	Accu-Chek Performa
Dimensions and weight:	Width: 52 mm Depth: 22 mm Height: 93 mm Weight: 60 grams
Components of the measurement system:	Blood glucose meter, Accu-Chek Softclix Lancing device
Measurand:	Mmol/L
Sample material:	Meter with battery, manual, 50 count strips, quick reference guide
Sample volume:	0,6 ul
Measuring principle:	electrochemical
Traceability:	Traceable to NIST standard
Calibration:	Calibrated using venous blood with 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:	0.6 mmol/L to 33.3 mmol/L
Linearity:	0.6 mmol/L to 33.3 mmol/L
Measurement duration:	5 sec
Operating conditions:	8 - 44 °C: 10 - 90 % humidity
Electrical power supply:	2 3 volt Lithium batteries
Recommended regular maintenance:	Weekly cleaning with soapy water or methanol
Package contents:	Meter, lancing device, 10 test strips, manual, quick reference guide
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?	500 test results and 20 control 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 Performa
Stability in unopened sealed vial:	18 months
Stability in opened vial:	Until date on the vial
Package contents:	50 test strips, strip insert, 1 code key

Table 4. Quality control

Electronic self check:	Yes
Recommended control materials and volume:	Performa controls (2 levels per package) 2.5 ml per vial
Stability in unopened sealed vial:	24 month from date of manufacture
Stability in opened vial:	3 months
Package contents:	2 levels per package: 2.5 ml per vial

Table 5. Marketing information

Manufacturer:	Roche Diagnostics
Retailers in Scandinavia:	Denmark: not in sale Norway: not in sale Sweden: not in sale
In which countries is the system marketed:	Globally × Scandinavia ☐ Europe ☐
Date for start of marketing the system in Scandinavia:	To be confirmed
Date for CE-marking:	June 2010 (strips) August 2007 (Performa Meter)
In which Scandinavian languages is the manual available:	Finish, Swedish, Norwegian, Danish

Raw data glucose, internal quality control, Accu-Chek Performa

Accu-Chek Performa Control	Lot-no	Expiry	Glucose level mmol/L
Control 1	10100323	2013-01-31	1,7 – 3,3
Control 2			14,5 – 19,6

Accu-Chek Performa Control,
analysed on the biomedical laboratory scientist's meter

Date	Control 1 glucose, mmol/L	Control 2 glucose, mmol/L
23.06.2011	2,6	17,6
24.06.2011	2,5	17,4
28.06.2011	2,6	17,4
29.06.2011	2,6	17,5
30.06.2011	2,6	16,9
05.07.2011	2,5	17,5
07.07.2011	2,6	17,6
09.08.2011	2,6	17,4
09.08.2011	2,6	17,3
10.08.2011	2,6	17,0
10.08.2011	2,7	17,5
11.08.2011	2,6	18,0
16.08.2011	2,6	17,0
17.08.2011	2,6	17,7
18.08.2011	2,6	17,7
23.08.2011	2,5	17,1

SKUP-info

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

Konklusjon
Presisjonen på Accu-Chek Performa var god. For glukosekonsentrasjoner < 10 mmol/L, samsvarte resultatene fra Accu-Chek Performa med resultatene fra en anerkjent sykehusmetode. For glukosekonsentrasjoner > 10 mmol/L var resultatene fra Accu-Chek Performa systematisk lavere enn resultatene fra sammenligningsmetoden. Avviket var ca. -0,5 mmol/L. Internasjonale kvalitetsmål fra ISO 15197, med et avvik mindre enn ± 20 % fra en anerkjent glukosemetode, ble oppnådd.

Accu-Chek Performa er beregnet til måling av blodsukker i ferskt fullblod. Systemet er produsert av Roche Diagnostics GmbH, og består av Accu-Chek Performa apparat og Accu-Chek Performa teststrimmel. Apparatet kodes ved hjelp av en kodebrikke. Apparatet slås automatisk på når man setter inn en teststrimmel. Det kreves 0,6 µL blod til hver måling. Målingen tar 5 sekunder. Accu-Chek Performa kan lagre 500 resultat. I Norge er Accu-Chek Performa kun i bruk blant helsepersonell.

Utprøvingen
Utprøvingen av Accu-Chek Performa ble utført under optimale betingelser av laboratorieutdannet personale. Glukoseresultatene fra Accu-Chek Performa ble sammenlignet med resultatene fra en anerkjent sykehusmetode. Det ble tatt prøver av 78 personer med diabetes og av 12 personer uten diabetes.

Resultater
Presisjonen på Accu-Chek Performa var god med en CV mellom 2,9 og 4,1 %. Resultatene fra Accu-Chek Performa samsvarte med resultatene fra sammenligningsmetoden for glukosekonsentrasjoner < 10 mmol/L. For glukosekonsentrasjoner > 10 mmol/L var resultatene fra Accu-Chek Performa systematisk lavere enn resultatene fra sammenligningsmetoden. Avviket var ca. -0,5 mmol/L. Kvalitetsmålet fra ISO 15197, 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 Performa, SKUP/2011/93*, 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/2011/93*	Glucose	Accu-Chek Performa	Roche Diagnostics
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/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-Chec 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/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
SKUP/2006/58	HbA1c	*Confidential*	
SKUP/2007/57*	PT (INR)	Simple Simon PT	Zafena AB
SKUP/2007/56*	PT (INR)	*Confidential*	
SKUP/2007/55	PT (INR)	CoaguChek XS	Roche Diagnostics
SKUP/2007/54*	Mononucleosis	*Confidential*	
SKUP/2006/53*	Strep A	*Confidential*	
SKUP/2005/52*	Strep A	*Clearview Exact Strep A Dipstick*	Applied Biotech, Inc.

*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

Comments from Roche to the SKUP report

Roche Diagnostics wishes to thank SKUP for performing a technical laboratory evaluation of the Accu-Chek® Performa Blood Glucose Monitoring System.
The evaluation was ordered to get an objective documentation of the optimal analytical quality of the test strip in combination with the Accu-Chek Performa meter, as part of necessary documentation required in a Swedish tender system. The evaluation has concluded that the systems meet the Quality goals according to ISO 15197.

Roche Diagnostics would like to thank the SKUP organization for their positive, helpful and professional behavior throughout the process. It has been a pleasure to work with the SKUP team during this evaluation of the Accu-Chek® Performa System.

Best regards

Jenny Hemingway

Roche Diagnostics Scandinavia AB