Atellica DCA Analyzer and Atellica DCA HbA1c Reagent Cartridges

A system for measurement of HbA1c and ACR manufactured by Siemens Healthcare Diagnostics, Inc.

An evaluation of the measurement of HbA1c

SKUP

Report from the evaluation

SKUP/2025/121

organised by SKUP at the request of Siemens Healthineers

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Attachments with raw data are included only in the copy to Siemens Healthineers.

1. Summary

Atellica DCA Analyzer and Atellica DCA HbA1c Reagent Cartridges, HbA1c

Manufacturer	Siemens Healthcare Diagnostics, Inc
Supplier in Denmark	Timik ApS
Supplier in Sweden	Timik AB
Supplier in Norway	Timik AS
Launched in Scandinavia	April 2024

Aim

To assess the analytical performance and user-friendliness of Haemoglobin A1c (HbA1c) measurements with the Atellica DCA HbA1c System performed by the intended users, i.e. experienced laboratory personnel and health care professionals in primary healthcare.

Performance specifications	Results	Conclusions
Repeatability CV ≤3,0 % calculated per site, each with results divided into three concentration interval.	Hospital laboratory: Capillary samples 2,4 – 3,9 CV% Venous samples 1,9 – 5,0 CV%	Inconclusive (fulfilled in clinically relevant interval (39-59 mmol/mol))
	Primary health care centres (PHCCs): Capillary samples 1,9 – 6,0 CV% Venous samples 2,3 – 2,9 CV%	Inconclusive (fulfilled in clinically relevant interval (39-59 mmol/mol))
Accuarcy ≥95 % of the results should be within ±3,0 mmol/mol from the results of the comparison method at HbA1c concentrations <35,3 mmol/mol and within ±8,5 % at HbA1c concentrations ≥35,3 mmol/mol	Hospital laboratory: Capillary samples 88 % Venous samples 89 %	Not fulfilled
	PHCCs: Capillary samples 84 % Venous samples 90 %	Not fulfilled
User-friendliness A total rating of "Satisfactory"	The user-friendliness was rated satisfactory.	Fulfilled

Additional information

Participants	Persons ≥18 years coming to the laboratory or the PHCC for measurement of HbA1c.
Evaluated method	Atellica DCA HbA1c System on capillary and venous whole blood using three lots of reagent cartridges.
Comparison method	Tosoh Automated Glycohemoglobin Analyzer HLC-723G11 from Tosoh Corporation, Inc., in the department of Laboratory Medicine, Hospital of Västmanland, Västerås, Sweden. Method adjusted with reference materials.
Technical error	1,2 %. The SKUP recommendation of <2 % was achieved.

A letter with comments from Siemens Healthineers is attached to the report.

Further information about the evaluation and the organisation of SKUP can be found on www.skup.org.
This summary is also published in Danish, Norwegian and Swedish at www.skup.org.

2. Abbreviations and Acronyms

ACR	Albumin/Creatinine Ratio
APS	Analytical Performance Specification
BLS	Biomedical Laboratory Scientist
C-NPU	Committee on Nomenclature, Properties and Units
CI	Confidence Interval
CV	Coefficient of Variation
DCCT	Diabetes Control and Complications Trial
DEKS	Danish Institute of External Quality Assurance for Laboratories in the Health Sector
DSKB	The Danish Society of Clinical Chemistry
EDTA	Ethylenediaminetetraacetic Acid
EQA	External Quality Assessment
Equalis	External quality assessment in laboratory medicine in Sweden
HbA1c	Haemoglobin A1c
HPLC	High Performance Liquid Chromatography
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
LC/MS	Liquid Chromatography/Mass Spectrometry
LIS	Laboratory Information System
NGSP	National Glycohaemoglobin Standardization Program
Noklus	Norwegian Organization for Quality Improvement of Laboratory Examinations
PHCC	Primary Health Care Centre
POC	Point of Care
SD	Standard Deviation
SKUP	Scandinavian Evaluation of Laboratory Equipment for Point of Care Testing
Swedac	Swedish board for accreditation and conformity assessment
VUK	Videnskabeligt Udvalg for Kvalitetssikring (Scientific committee for quality assurance in Denmark)

3. Introduction

The purpose of Scandinavian evaluation of laboratory equipment for point of care testing (SKUP) is to improve the quality of near patient testing in Scandinavia by providing objective information about analytical performance and user-friendliness of laboratory equipment. This information is generated by organising SKUP evaluations in point of care (POC) settings.

3.1. The concept of SKUP evaluations

SKUP evaluations follow common guidelines and the results from various evaluations are comparable[1]. The evaluation set-up and details are described in an evaluation protocol and agreed upon in advance. The analytical results and user-friendliness are assessed according to pre-set performance specifications. To fully demonstrate the performance of a product, the intended users should be involved in the evaluation. If possible, SKUP evaluations are carried out using three lot numbers of reagent cartridges from separate and time-spread productions. Some evaluation codes are followed by an asterisk (*), indicating an evaluation with a more specific objective. The asterisk is explained on the front page of these protocols and reports.

3.2. Background for the evaluation

The Atellica DCA Analyzer system is an in vitro diagnostic device for the quantitative measurement of Haemoglobin A1c (HbA1c) and Albumin/Creatinine ratio (ACR). The product is intended for professional use. The sample materials for HbA1c measurement are capillary and venous whole blood. The measuring system is produced by Siemens Healthcare Diagnostics, Inc. and was launched into the Scandinavian market in April 2024. The SKUP evaluation was carried out December 2024 to February 2025 at the request of Siemens Healthineers in USA.

3.3. The aim of the evaluation

The aim of the evaluation was to assess the analytical performance and user-friendliness of Atellica DCA Analyzer and Atellica DCA HbA1c Reagent Cartridges hereafter called “the Atellica DCA HbA1c System” in the hands of the intended users; healthcare professional in clinical laboratories and in POC settings.

3.4. The model for the evaluation of the Atellica DCA HbA1c System

SKUP evaluations for quantitative methods are based upon the fundamental guidelines in a book concerning evaluations of laboratory equipment in primary health care [1]. This evaluation consisted of two parts (figure 1). One part of the evaluation was carried out by experienced laboratory personnel in a hospital laboratory. The other part of the evaluation was carried out by health care professionals in primary health care centers (PHCCs). Both parties represented the intended users of the measuring system.

The evaluation included:

- Examination of the analytical performance (precision and accuracy) in the hands of experienced laboratory personnel in a hospital laboratory, using both capillary and venous whole blood samples.
- Examination of the analytical performance (precision and accuracy) in the hands of healthcare professionals in PHCCs, using both capillary and venous whole blood samples.
- Evaluation of the user-friendliness of the Atellica DCA HbA1c System and its manual by the intended users.

[1]SKUP evaluations are under continuous development. In some cases, it may be difficult to compare earlier protocols, results and reports with more recent ones.

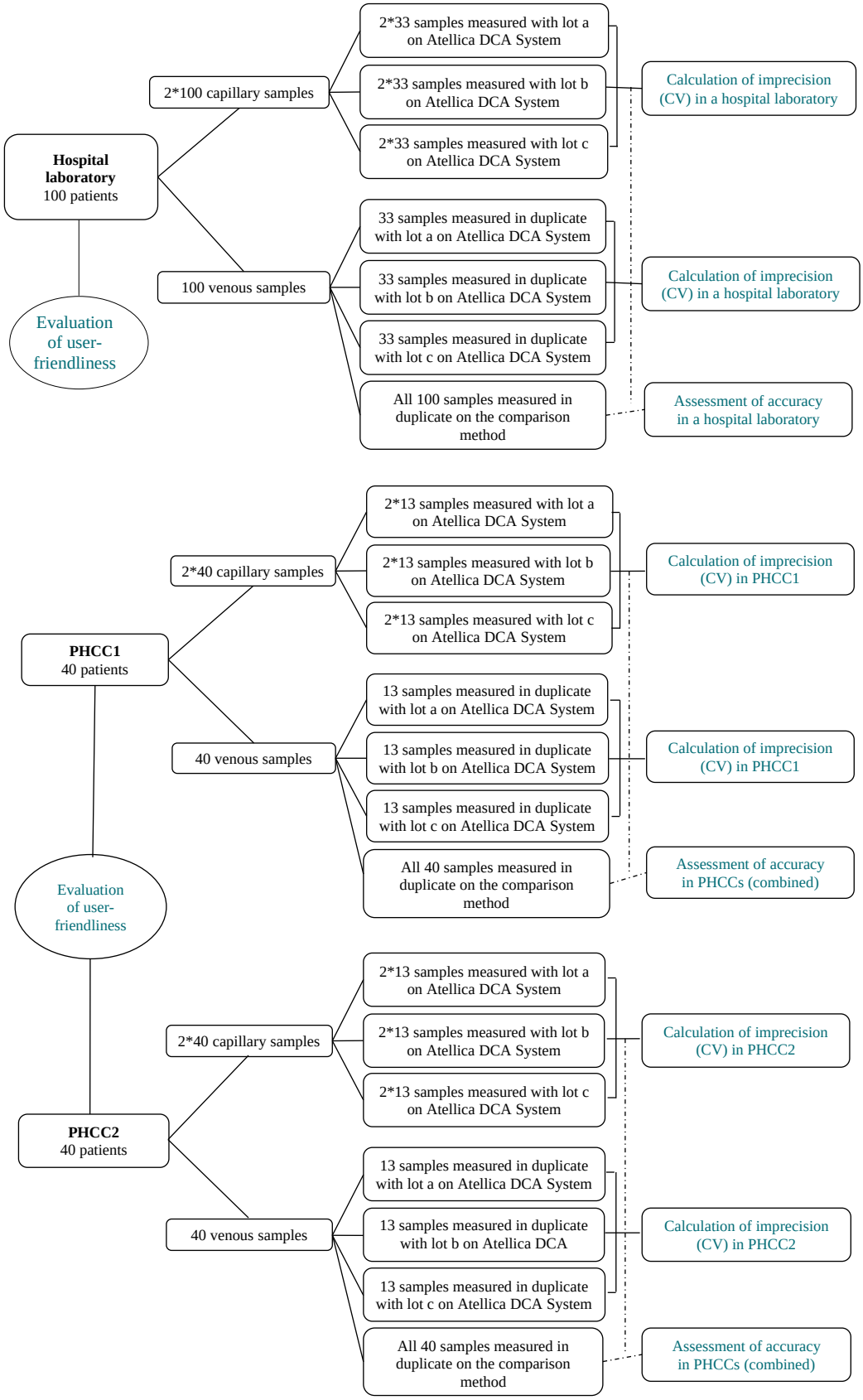

Figure 1. Flowchart illustrating the model for the evaluation of the Atellica DCA HbA1c System in capillary and venous samples.

4. Performance specifications

4.1. Analytical performance specifications

The analytical performance specifications (APSs) in this evaluation are based on HbA1c results expressed in mmol/mol (IFCC units; International Federation of Clinical Chemistry and Laboratory Medicine). APSs specified for HbA1c results in mmol/mol must be recalculated to APSs for results expressed in National Glycohaemoglobin Standardization Program (NGSP) units. Weycamp *et al.* have explained why the APSs for HbA1c measurement in mmol/mol and the Diabetes Control and Complications Trial (DCCT) % are different [2].

The Danish Society of Clinical Chemistry (DSKB) has a scientific committee for quality assurance Videnskabeligt Udvalg for Kvalitetssikring (VUK). In 2011, the committee specified the following APSs for HbA1c mmol/mol when used for diagnosis and monitoring of diabetes in Denmark [3, 4]:
Maximum allowable imprecision CV (coefficient of variation): 2,8 %
Maximum allowable bias at HbA1c level 48 mmol/mol: ±2,8 %
Maximum allowable deviation at HbA1c level 48 mmol/mol: ±7,3 % (requirement for deviation from true target).
In 2021, the committee specified APSs for HbA1c mmol/mol for POC testing assessment by SKUP when used for diagnosis of diabetes [5]: The imprecision shall be ≤3 % and for the accuracy, at least 95 % of the individual HbA1c results shall fall within ±3,0 mmol/mol of the average measured values of the reference measurement procedure at HbA1c concentrations <35,3 mmol/mol or within ±8,5 % at HbA1c concentrations ≥35,3 mmol/L.

The Norwegian Directorate of Health has specified APSs for diagnostic use of HbA1c. The HbA1c method must be traceable to the IFCC reference method, and a deviation ≤±7,4 % from reference target at a level of 48 mmol/mol and a CV <3 % must be documented [6, 7].

In Sweden, the national APSs are set up by External quality assessment in laboratory medicine in Sweden's (Equalis) advisory group for protein analysis and were approved by the Swedish Association for Clinical Chemistry in 2010 [8].
Maximum bias: ±1,5 mmol/mol
Between-laboratories-variation (CV): 2,5 %
Allowable deviation: bias ± 1,65 × standard deviation (SD) ~ bias ± 1,65 × 0,025 × HbA1c level
Thus, the allowable deviation at 48 mmol/mol is ≤±3,5 mmol/mol.

Based on the national practices, SKUP chose to use a requirement of 3 % for imprecision and to follow VUK for the APS of accuracy. SKUP's APSs for HbA1c in this evaluation were as presented in section 4.4.

4.2. User-friendliness

The evaluation of user-friendliness was carried out by asking the evaluating persons in the PHCCs and the hospital laboratory to fill in a questionnaire, see section 6.5.

Technical errors
SKUP recommends that the fraction of tests wasted due to technical errors should not exceed 2 %.

4.3. SKUP's performance specifications in this evaluation

As agreed upon when the protocol was drawn up, the results from the evaluation of Atellica DCA HbA1c System are assessed against the following performance specifications:

Repeatability (CV)..... ≤3,0 %

Allowable deviation of the individual result from the comparison method result

for HbA1c concentrations <35,3 mmol/mol ..... ≤±3,0 mmol/mol

and for HbA1c concentrations ≥35,3 mmol/mol ..... ≤±8,5 %

Required percentage of individual results
within the allowable deviations..... ≥95 %

User-friendliness, overall rating..... Satisfactory

The results in this evaluation will only be presented in mmol/mol.
Results can be recalculated between the two units with the following equations:
HbA1c (IFCC, mmol/mol) = 10,93 × HbA1c (NGSP, %) – 23,54
HbA1c (NGSP, %) = 0,0915 × HbA1c (IFCC, mmol/mol) + 2,153

4.4. Principles for the assessments

For a measuring system to be considered good in a SKUP evaluation, the system had to show satisfactory analytical performance as well as satisfactory user-friendliness.

4.4.1. Assessment of the analytical performance

The analytical results were assessed according to pre-set APSs.

Precision

The decision whether the achieved CV fulfils the APS or not, was made on a 5 % significance level (one-tailed test). The distinction between the ratings, and the assessment of precision according to the APS, are shown in table 1. Based on the results from each evaluation site, an overall conclusion was drawn in the summary of the report. The overall conclusion in the summary was drawn based on the following principles: If the precision at all sites was fulfilled/most likely fulfilled, the overall conclusion was *fulfilled*. If the precision at all sites was not fulfilled/most likely not fulfilled, the overall conclusion was *not fulfilled*. If there is a combination of fulfilled/most likely fulfilled/most likely not fulfilled/not fulfilled, the overall conclusion was *inconclusive*.

Table 1. The rating of precision.

Distinction between the ratings	Assessment according to the APS
The CV is equal to or lower than the APS (statistically significant)	The APS is fulfilled
The CV is equal to or lower than the APS (not statistically significant)	Most likely the APS is fulfilled
The CV is higher than the APS (not statistically significant)	Most likely the APS is not fulfilled
The CV is higher than the APS (statistically significant)	The APS is not fulfilled

Bias
SKUP did not set a separate APS for bias. The confidence interval (CI) of the measured bias was used for deciding if a difference between the evaluated method and the comparison method was statistically significant (two-tailed test, 5 % significance level). The bias was also discussed in connection with the accuracy.

Accordance between lot numbers
Separate lot-to-lot calculations were not performed. The results achieved with the three lots of reagent cartridges are visually shown in the assessment of accuracy in the difference plot for the results achieved by experienced laboratory personnel. If there are distinct differences between the lots, this is pointed out and discussed.

Accuracy
The accuracy was illustrated in difference plots with limits for the allowable deviation according to the APS. The fraction of results within the limits was counted. The accuracy was assessed as either fulfilling the APS or not fulfilling the APS.

4.4.2. Assessment of the user-friendliness

The user-friendliness was assessed according to the answers and comments given in the questionnaire (see section 6.5). For each question, the evaluator could choose between three given ratings; satisfactory, intermediate and unsatisfactory, or the evaluator could mark the choice no opinion. The responses from the evaluators were reviewed and summed up. To achieve the overall rating “satisfactory”, the tested equipment had to reach a total rating of “satisfactory” in all four subareas of characteristics described in section 6.5.

Technical errors
The evaluating persons register error codes, technical errors and failed measurements during the evaluation. The fraction of tests wasted due to technical errors was calculated and taken into account in connection with the assessment of the user-friendliness. User errors were not included in the calculation.

5. Materials and methods

5.1. Definition of the measurand

The measurement systems intend to measure the substance fraction of glycated haemoglobin per mol of haemoglobin in whole blood. For the evaluated system the sample material is fresh capillary whole blood and venous ethylenediaminetetraacetic acid (EDTA) blood and for the comparison method the sample material is venous EDTA blood. The results are traceable to the IFCC reference method and are expressed in the unit mmol/mol. The Committee on Nomenclature, Properties and Units (C-NPU) systematically describes clinical laboratory measurands in a database [9]. The NPU code related to the measurand in this evaluation is NPU27300. Some parts of the world only accept HbA1c results in NGSP unit, which is specified in NPU03835. In this report the term HbA1c will be used for the measurand.

5.2. The evaluated measuring system Atellica DCA HbA1c

The information in this section derives from the company's information material.

Atellica DCA Analyzer (figure 2) and Atellica DCA HbA1c Reagent Cartridges is a system for measurement of HbA1c. Reagent cartridges for urine ACR are also available for the Atellica DCA Analyzer. The Atellica DCA system is intended for professional use in POC settings and clinical laboratories.

Figure 2. The Atellica DCA Analyzer

The measuring system contains a dual-beam, multi-wavelength spectrometer. Closed loop, temperature-controlled heater plates allow for detection of thermal runaway and will also detect, and flag, if the user run a test cartridge below the specified temperature. The barcode on the test cartridge contains test- and lot-specific information. No separate calibration is needed.
The Atellica DCA modular design allows connection of up to three modules to a single display.

The sample is collected into a capillary holder by capillary force, either from a small drop of capillary blood from a finger prick or from the stopper on a sample tube with venous whole blood. The capillary holder and the reagent cartridge are individually packed and thereafter packed together in a box. The results are presented in mmol/mol or NGSP %. The Atellica DCA HbA1c Control kit is available at two levels; normal and abnormal.

For technical details about the Atellica DCA HbA1c System, see table 2. For more information about the Atellica DCA HbA1c System, and name of the manufacturer and the suppliers in the Scandinavian countries, see attachment 1 and 2. For product specifications in this evaluation, see attachment 3.

Table 2. Technical details from the manufacturer.

Technical details for the Atellica DCA HbA1c System	
Sample material	Capillary and venous whole blood
Sample volume	1 µL
Measuring time	5 minutes
Measuring range	20 – 130 mmol/mol
Laboratory information system (LIS) communication	Yes
Storage capacity	10 000 patient test results and 5000 quality control results

External analytical quality assurance
External quality assessment (EQA) programs aim to ensure the analytical quality for measurement of various analytes. In the Scandinavian countries, EQA programs for HbA1c measurements on POC systems are available from Equalis (Sweden) and Norwegian Organization for Quality Improvement of Laboratory Examinations (Noklus, Norway). Danish users of HbA1c POC equipment use either split-sample testing in their region or participate in an EQA program from Labquality/Aurevia (Finland).

5.3. The selected comparison method

A selected comparison method is a fully specified method which serves as a common basis for the comparison of the evaluated method. The selected comparison method in this evaluation is adjusted according to a reference material, see 5.3.2.

5.3.1. The selected comparison method in this evaluation

The selected comparison method in this evaluation was Tosoh Automated Glycohemoglobin Analyzer HLC-723G11 from Tosoh Corporation, Inc., hereafter called “the comparison method”, in the department of Laboratory Medicine, Hospital of Västmanland Västerås, Sweden. The method is accredited according to SS-EN ISO15289 by the Swedish board for accreditation and conformity assessment (Swedac).

Principle: High performance liquid chromatography (HPLC)
Column: TSK gel G11 Variant
Reagent: Elution buffer HSi Variant No.1, No.2, No.3, hemolyzing solution and wash solution
Traceability: Traceable to IFCC method and reference materials developed by IFCC Working group on Standardization of HbA1c [10]
Calibrators: Haemoglobin A1c calibrator set, Tosoh Corporation, Inc.
Measurement range: 6 – 196 mmol/mol

Internal analytical quality control
Internal analytical quality control samples, two levels (Lyphochek Diabetes Control, Bio-Rad), was measured each evaluation day on the comparison method.

External analytical quality control
The clinical laboratory participates in Equalis EQA scheme for HbA1c with one level in ten rounds per year. The assigned value for HbA1c is based on a consensus value of the largest output groups.

5.3.2. Verification of the analytical performance of the comparison method

Precision
The repeatability (CV) of the comparison method was calculated from duplicate measurements of venous samples from the participants recruited at the hospital laboratory.

Trueness
Fresh frozen venous patient samples with HbA1c concentrations at four levels were used to assess the trueness of the comparison method. The samples have target values determined with an IFCC liquid chromatography/mass spectrometry (LC/MS) reference method procedure at INSTAND, Germany [11]. The target values are given with an expanded uncertainty of <2 % (k=2). If necessary, the comparison method's results are adjusted according to the certified INSTAND targets. The adjustment is carried out by means of inverse calibration [12, 13]. In addition, the trueness of the comparison method was confirmed with EQA results for a period circumventing the evaluation period.

5.4. The evaluation

5.4.1. Planning of the evaluation

Inquiry about an evaluation
Siemens Healthineers via Rajesh Krishnan, Point of Care Diagnostics Portfolio Management, applied to SKUP for an evaluation of the Atellica DCA HbA1c System.

Protocol, arrangements and contract
In June 2024, the protocol for the evaluation was approved, and Siemens Healthineers and SKUP signed a contract for the evaluation. Laboratory personnel at the laboratory of Hospital of Västmanland Fagersta, Sweden, were assigned to do the practical work with the Atellica DCA Hba1c System in the evaluation at the hospital laboratory. Two PHCCs, Närvården City and Närvården Viksäng-Irsta in Västerås, region Västmanland, were assigned to do the practical work with the Atellica DCA Hba1c System in the evaluation in the primary health care. Both parties represent intended users of the measuring system.

Training
The training of all three evaluation sites was performed by the supplier Timik AB with the help of Siemens Healthineers in December 2024. The training in the PHCCs reflected the training usually given to the end-users. Siemens Healthineers and Timik were not allowed to contact or supervise the evaluators during the evaluation period.

5.4.2. Evaluation sites and persons involved

The practical work was carried out during seven weeks at the hospital laboratory and five weeks in the PHCCs, ending in February 2025. The hospital laboratory is part of a regional hospital.
At the hospital laboratory two biomedical laboratory scientists (BLSs) and one assistant nurse were involved in the practical work with the evaluation of the Atellica DCA HbA1c System.

PHCC1 is a large center with 14 978 listed patients. From PHCC1 two assistant nurses participated in the evaluation. They use venous samples in their routine method for measurements of HbA1c, sending the samples to the department of Laboratory Medicine in Västerås for analysis. They are familiar in collecting capillary samples for other measurands. PHCC2 is a large center with 15 600 listed patients. From PHCC2 three assistant nurses participated in the evaluation. As their routine method for measuring HbA1c they use capillary samples on a POC-instrument.

The comparison method was performed at department of Laboratory Medicine, Hospital of Västmanland, Västerås, Sweden. This is the largest hospital in the region, and the laboratory has 210 employees. All BLSs in the laboratory was involved in analysing the samples, one BLS student was collecting and reporting the results to SKUP, and one clinician was coordinating and supervising the evaluation.

5.4.3. The evaluation procedure

Instrumentation

Each of the evaluating sites received two Atellica DCA Analyzers. One of them was dedicated to measurements of capillary patient samples, and the other dedicated to measurements of venous patient samples.

Internal analytical quality control

Internal analytical quality control samples for the Atellica DCA HbA1c System, two levels (Atellica DCA Analyzer HbA1c Controls, Siemens Healthcare Diagnostic, Inc.), were measured each evaluation day on the Atellica DCA HbA1c System in the hospital laboratory, at least one level per instrument, alternating the levels between the two instruments. In the PHCCs the control samples were measured each evaluation day on the Atellica DCA System, one level per day on both instruments, alternating between the two levels at different days. The reproducibility (CV) as achieved with the quality control material was calculated.

Recruitment of participants and ethical considerations

People ≥18 years coming into the laboratory/PHCCs for HbA1c measurements were asked if they were willing to donate two capillary and one venous blood sample for the evaluation. Persons with known hemoglobinopathies were not included.

The participants were selected to cover a wide range of HbA1c concentrations; if possible, approximately 10 % of samples with HbA1c <39 mmol/mol (screening samples), approximately 70 % in the interval 39 – 59 mmol/mol and approximately 20 % of the samples >59 mmol/mol.

No personal information of the participants was obtained. Privacy protection of the participants was secured and no result in the evaluation could be traced to the individual participant. An ethical approval was not necessary because the evaluation is considered a quality assurance project.

Handling of the samples and measurements

Both capillary and venous whole blood samples were used for measurement with the Atellica DCA HbA1c System. The puncture site was disinfected with alcohol pads and the area dried completely before sampling. Disposable lancing devices (Safety-Lanzette Mini 28G from Sarstedt or Safe-T-Lance 21G from ICU Medical) with depth settings 1,6 mm or 1,8 mm, respectively, were used for collection of capillary samples. Venous samples were obtained by venous puncture

and collected into 4 mL vacutainer tubes with K_2-EDTA (Vacutainer from BD or Vacuette from Greiner bio-one).

The second drop of capillary blood was measured on the Atellica DCA HbA1c System in accordance with the instructions from the manufacturer. Two capillary samples were measured immediately in after each other on one of the two Atellica DCA HbA1c Systems. In case of error codes, the test was repeated if possible until a result was obtained.
The venous sample was mixed by either inversion of the tube 5-10 times or on a tilting table and then measured as soon as possible, in duplicate after each other, on the other of the two Atellica DCA HbA1c Systems. In case of error codes, the test was repeated if possible until a result was obtained. Three lot numbers of reagent cartridges were used in the evaluation.

Samples for the comparison method were obtained from venous puncture and collected into 4 mL vacutainer tubes with K_2-EDTA (Vacutainer from BD or Vacuette from Greiner bio-one). The tubes were inverted 5 – 10 times to ensure thorough mixing and kept at room temperature or in refrigerator until transported to the department of Laboratory Medicine later the same day or the day after, respectively. If possible, the same tube was used for venous measurements on the Atellica DCA HbA1c System. Confirmed specimen stability is seven days at 4 – 8°C, but the department of Laboratory Medicine measured the venous blood samples in duplicate for HbA1c on the comparison method within 72 hours after collection. All samples were treated according to the internal procedures of the clinical laboratory regarding potential interfering substances.

6. Results and discussion

Statistical expressions and calculations used by SKUP are shown in attachment 4.

6.1. Number of samples

Scheduled number of samples in this evaluation was capillary and venous samples, measured in duplicates, collected from 100 participants at the hospital laboratory and 40 participants at each PHCC. In the end the hospital laboratory collected samples from 102 participants (SKUP IDs 101-202), PHCC1 from 51 participants (SKUP IDs 301-351) and PHCC2 from 40 participants (SKUP IDs 401-440). An account of the number of samples not included in the calculations is given below.

Missing results
Comparison method: Only single value for SKUP ID 337.

Atellica DCA HbA1c System:
- Capillary sample results; only single value for SKUP ID 111, 131, 133-135, 148, 149, 153, 171, 173, 181, 189, 192 and 200 from the hospital laboratory. Only single value for SKUP ID 303, 304, 332, 337 and 350 from PHCC1. Most of the single results were due to user- or technical errors or that the patient left before the collection of either the second sample or a remeasurement.

- Venous sample results; only single value for SKUP ID 301-305, due to a misunderstanding by personnel, and SKUP ID 315 from PHCC1.

Omitted results
SKUP ID 427 (PHCC2) capillary sample 2 was omitted due to the result being above the measuring range.

Excluded results (statistical outliers)
Statistical outliers in SKUP evaluations are detected by the criterion promoted by Burnett [14].

Comparison method: SKUP ID 115, 156 and 440 were statistical outliers in the calculation of repeatability. These IDs were excluded from the calculations of bias and accuracy, but the results from the Atellica DCA HbA1c System was included in the calculation of the systems' repeatability.

Atellica DCA HbA1c System:
- Capillary sample results; SKUP ID 201 was an outlier in the calculation of repeatability. This ID was excluded from the calculation of bias, but the first result was included in the calculation of accuracy.

- Venous sample results; SKUP ID 107 and 186 were outliers in the calculation of repeatability. These IDs were excluded from the calculation of bias, but the first results were included in the calculation of accuracy. SKUP ID 305 (single value) was an outlier in the calculation of bias and this extreme value was not included in the calculation of accuracy since it most likely was a handling error.

Recorded error codes, technical errors and failed measurements
In total 765 patient samples and 146 internal quality control samples were analysed. There were 11 error codes reported, all deemed as technical errors, which constitutes 1,2 %. The SKUP recommendation of a fraction of ≤2 % tests wasted due to technical errors was achieved.

6.2. Analytical performance of the selected comparison method

6.2.1. Internal analytical quality control

All results from the internal analytical quality control (Lyphochek Diabetes Control, Bio-Rad), two levels, were within the allowable control limits (data not shown).

6.2.2. The precision of the comparison method

Duplicate measurements of each venous sample from the hospital laboratory were performed on the comparison method. Two instruments were used for the measurements, but each individual sample was analysed in duplicate on the same instrument. The results were checked visually to meet the imposed condition for using formula 1 in attachment 4. There were no systematic differences pointed out between the paired measurements (data not shown).

The imprecision (CV) of the comparison method, with a 90 % CI, is shown in table 3. The results were sorted and divided into three concentration intervals according to the mean of the results. Raw data is attached for the requesting company only, see attachment 5.

Table 3. Imprecision (CV) of the comparison method for HbA1c measured in venous samples.

Interval, mmol/mol	n*	Excluded results (statistical outliers)	Mean value HbA1c, mmol/mol	CV (90 % CI), %
<39	14	0	35,5	1,3 (1,0 – 1,9)
39 – 59	59	2**	47,8	0,5 (0,5 – 0,6)
>59	29	0	73,4	0,4 (0,4 – 0,6)

*The given number of results (n) were counted before the exclusion of statistical outliers. Mean and CV were calculated after the exclusion of statistical outliers. An account of the number of samples is given in section 6.1.
**ID 115 and ID 156 were statistical outliers according to Burnett's model [14] in the calculation of repeatability and therefore excluded.

Discussion
The CV for the comparison method was between 0,4 and 1,3 %.

6.2.3. The trueness of the comparison method

To demonstrate the trueness of the comparison method, four levels of fresh frozen venous patient samples with assigned values from a reference method procedure at INSTAND were measured on both instruments used for the comparison method. The measurements were performed in triplicate on three different occasions: start-up, halfway through and at the end of the evaluation. The agreement between the comparison method and the samples with assigned reference values is shown in table 4.

Table 4. Samples with reference values measured on the comparison method.

Material	Date	Assigned HbA1c values INSTAND, mmol/mol	n*	Mean value HbA1c, comparison method, mmol/mol		Deviation from target value, %	
				Instr. 1	Instr. 2	Instr. 1	Instr. 2
Level 1	2024-12-16	**29,1** (28,7 – 29,5)	3	30,7	30,6	+5,1	+5,0
	2025-01-23		3	30,9	29,8	+5,8	+2,5
	2025-02-14		3	30,2	30,5	+3,7	+4,5
	Total		**9**	**30,8**	**30,2**	**+5,5**	**+3,7**
Level 2	2024-12-16	**48,4** (47,7 – 49,1)	3	50,4	50,4	+4,0	+3,9
	2025-01-23		3	50,7	49,7	+4,6	+2,6
	2025-02-14		3	50,1	49,9	+3,5	+3,1
	Total		**9**	**50,6**	**50,0**	**+4,3**	**+3,2**
Level 3	2024-12-16	**57,2** (56,3 – 58,1)	3	60,2	60,0	+5,0	+4,6
	2025-01-23		3	60,6	59,4	+5,6	+3,8
	2025-02-14		3	59,7	59,8	+4,2	+4,3
	Total		**9**	**60,4**	**59,7**	**+5,3**	**+4,2**
Level 4	2024-12-16	**79,6** (78,4 – 80,8)	3	83,7	83,2	+4,9	+4,3
	2025-01-23		3	83,9	82,0	+5,1	+3,0
	2025-02-14		3	82,2	83,0	+3,2	+4,1
	Total		**9**	**83,8**	**82,6**	**+5,0**	**+3,7**

*Number of measurements, n, per instrument at each level and occasion.

Discussion

The HbA1c measurements for the reference samples on the comparison method showed results above the upper uncertainty limit for all levels. All results from the comparison method were adjusted according to the assigned values from INSTAND. The adjustment was carried out by means of inverse calibration [10, 11] by the following regression equations:

y = 0,9566x + 0,0993 (for measurements performed on instrument 1) or

y = 0,9606x + 0,0776 (for measurements performed on instrument 2).

Further on in the report, all results from the comparison method have been adjusted accordingly.

The trueness of the comparison method was confirmed by EQA results for a period circumventing the evaluation. Both instruments were within the APS in each of the three EQA rounds scheduled during the evaluation period (data not shown). Since both instruments measured higher than the assigned values in each round, the adjustment to lower values in this evaluation is deemed a correct action.

6.3. Analytical performance of the Atellica DCA HbA1c System at the hospital laboratory

The results below reflect the analytical performance of the Atellica DCA HbA1c System when used by experienced laboratory personnel at the hospital laboratory.

6.3.1. Internal analytical quality control

All results from the internal analytical quality control (Atellica DCA Analyzer HbA1c Controls), two levels, were within the allowable control limits (data not shown). The total reproducibility (CV) achieved with the internal analytical quality control material on the two Atellica DCA HbA1c Systems placed in the hospital laboratory were 4,4 % for level 1 (n=35) and 3,8 % for level 2 (n=36). The reproducibility for each Atellica DCA HbA1c System were 4,1 % and 4,9 %,

respectively, for level 1 (n=19 and 16) and 4,1 % and 3,7 %, respectively, for level 2 (n=17 and 19). Raw data is attached for the requesting company only, see attachment 6.

6.3.2. The precision of the Atellica DCA HbA1c System

Measurements were performed with two capillary samples from each participant on the Atellica DCA HbA1c System (instrument SMS0069). Duplicate measurements from each venous sample were performed on the Atellica DCA HbA1c System (instrument SMS3940). The results were checked visually to meet the imposed condition for using formula 1 in attachment 4. There were no systematic differences pointed out between the paired measurements (data not shown).

The precision is presented as repeatability (CV). The CV with a 90 % CI is shown in table 5 and 6. The results were sorted and divided into three concentration intervals according to the mean of the results of the Atellica DCA HbA1c System. Raw data is attached for the requesting company only, see attachment 7.

Table 5. Repeatability (CV) of the Atellica DCA HbA1c System for HbA1c measured in capillary samples. Results achieved by experienced laboratory personnel at a hospital laboratory.

Interval, mmol/mol	n*	Excluded results (statistical outliers)	Mean value HbA1c, mmol/mol	CV (90 % CI), %	APS (≤3,0 %) fulfilled
<39	21	0	33,9	3,9 (3,1 – 5,3)	No
39 – 59	43	1**	44,7	2,4 (2,0 – 2,9)	Yes
>59	24	0	70,7	3,4 (2,7 – 4,5)	Most likely not

*The given number of results (n) were counted before the exclusion of statistical outliers. Mean and CV were calculated after the exclusion of statistical outliers. An account of the number of samples is given in section 6.1.
**ID 201 was a statistical outlier according to Burnett's model [14] in the calculation of repeatability and therefore excluded.

Table 6. Repeatability (CV) of the Atellica DCA HbA1c System for HbA1c measured in venous samples. Results achieved by experienced laboratory personnel at a hospital laboratory.

Interval, mmol/mol	n*	Excluded results (statistical outliers)	Mean value HbA1c, mmol/mol	CV (90 % CI), %	APS (≤3,0 %) fulfilled
<39	20	0	33,3	5,0 (4,0 – 6,8)	No
39 – 59	56	2**	46,0	2,4 (2,1 – 2,8)	Yes
>59	26	0	71,2	1,9 (1,6 – 2,5)	Yes

*The given number of results (n) were counted before the exclusion of statistical outliers. Mean and CV were calculated after the exclusion of statistical outliers. An account of the number of samples is given in section 6.1.
**ID 107 and ID 186 were statistical outliers according to Burnett's model [14] in the calculation of repeatability and therefore excluded.

Discussion
The CV achieved by experienced laboratory personnel at the hospital laboratory was between 2,4 and 3,9 % depending on the interval for capillary samples and between 1,9 and 5,0 % depending on the interval for venous samples. For capillary samples, the repeatability was statistically significant below the APS in the mid-interval and above, but not statistically significant above at the highest interval. The repeatability for capillary samples was statistically significant above the APS at the lowest interval. For venous samples, the repeatability was statistically significant below the APS in the mid- and high intervals, and statistically significant above the APS at the lowest interval.

Conclusion
When used by experienced laboratory personnel at the hospital laboratory the APS for repeatability (CV ≤3,0 %) was fulfilled using capillary samples at the clinically important HbA1c interval 39–59 mmol/mol, most likely not fulfilled at HbA1c interval >59 mmol/mol, and not fulfilled at HbA1c interval <39 mmol/mol. For venous samples the APS for repeatability was fulfilled at the clinically important HbA1c interval 39–59 mmol/mol, as well as HbA1c interval >59 mmol/mol, but not fulfilled at HbA1c interval <39 mmol/mol.

6.3.3. The bias of the Atellica DCA HbA1c System

The mean deviation (bias) of the results from the Atellica DCA HbA1c System from the comparison method results was calculated. The bias is presented with a 95 % CI in table 7 and 8. The results were sorted and divided into three concentration intervals according to the mean results of the comparison method. Raw data is attached for the requesting company only, see attachment 5 and 7.

Table 7. Bias of the Atellica DCA HbA1c System for HbA1c measured in capillary samples. Results achieved by experienced laboratory personnel at a hospital laboratory.

Interval, mmol/mol	n	Excluded results (statistical outliers)	Mean value Comparison method, HbA1c, mmol/mol	Mean value Atellica DCA, HbA1c, mmol/mol	Bias (95 % CI), mmol/mol	Bias, %
<39	15	0	34,2	32,4	-1,8 ((-2,9) – (-0,8))	-5,3
39 – 59	56	0	46,0	44,4	-1,6 ((-2,1) – (-1,1))	-3,4
>59	28	0	70,8	69,4	-1,4 ((-2,3) – (-0,5))	-2,0

An account of the number of samples is given in section 6.1.

Table 8. Bias of the Atellica DCA HbA1c System for HbA1c measured in venous samples. Results achieved by experienced laboratory personnel at a hospital laboratory.

Interval, mmol/mol	n	Excluded results (statistical outliers)	Mean value Comparison method, HbA1c, mmol/mol	Mean value Atellica DCA, HbA1c, mmol/mol	Bias (95 % CI), mmol/mol	Bias, %
<39	14	0	34,0	31,5	-2,5 ((-3,4) – (-1,5))	-7,2
39 – 59	56	0	46,0	44,8	-1,2 ((-1,7) – (-0,7))	-2,6
>59	28	0	70,8	70,3	-0,6 ((-1,5) – (-0,3))	-0,8

An account of the number of samples is given in section 6.1.

Discussion

The bias achieved by experienced laboratory personnel at the hospital laboratory was between -5,3 and -2,0 % for capillary samples and between -7,2 and -0,8 % for venous samples. A significant difference could be seen between the methods for both sample types, where the results from the Atellica DCA HbA1c System were systematically lower than the results from the comparison method.

6.3.4. The accuracy of the Atellica DCA HbA1c System

To evaluate the accuracy of HbA1c results on the Atellica DCA HbA1c System, the agreement between the Atellica DCA HbA1c System and the comparison method is illustrated in difference plots (figure 3 and 4). The limits for the allowable deviation according to the APS (≤±3,0 mmol/mol for HbA1c concentrations <35,3 mmol/mol and ≤±8,5 % for HbA1c concentrations ≥35,3 mmol/mol), are shown with stippled lines. The first capillary and venous measurement, respectively, from the Atellica DCA HbA1c System are included in the plot. The plot illustrates both random and systematic errors, reflecting the total measuring error in the Atellica DCA HbA1c System results. Raw data is attached for the requesting company only, see attachment 5 and 7.

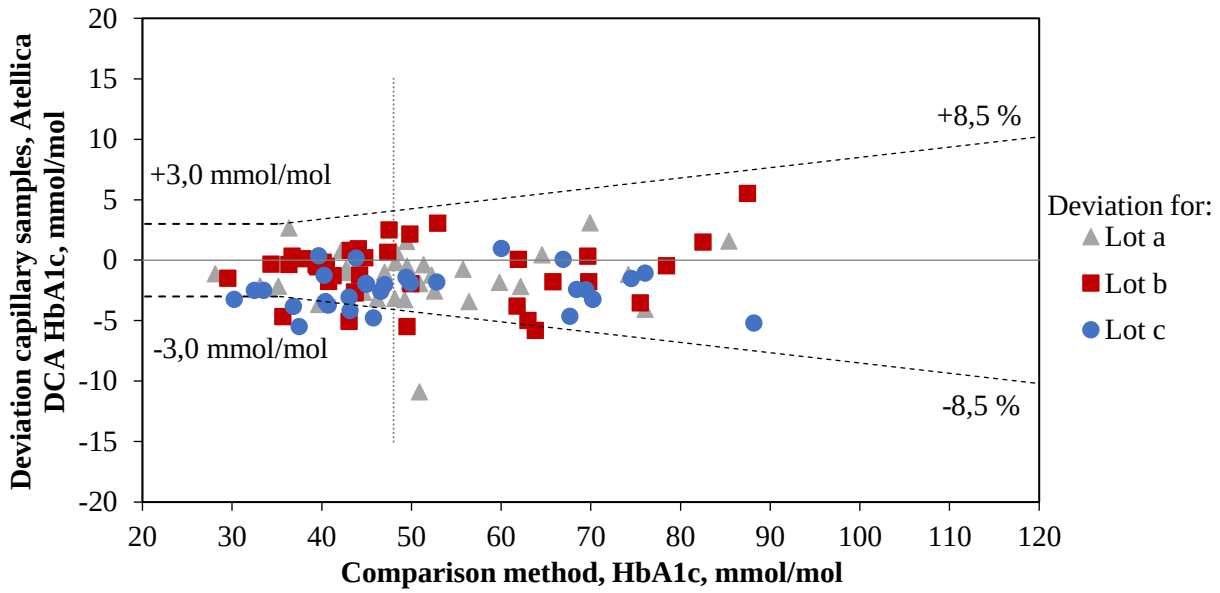

Figure 3. Accuracy of HbA1c results on the Atellica DCA HbA1c System achieved by experienced laboratory personnel at a hospital laboratory. The x-axis represents the mean HbA1c result of the comparison method. The y-axis represents the HbA1c deviation in mmol/mol of the first capillary sample measurement on the Atellica DCA HbA1c System from the mean result of the corresponding sample of the comparison method. The vertical line at 48 mmol/mol HbA1c illustrates the diagnostic threshold value for diabetes. The different lots of reagent cartridges are illustrated with the symbols ▲ (Lot a), ■ (lot b) and ● (lot c). Stippled lines represent the allowable deviation limits of ≤±3,0 mmol/mol for HbA1c concentrations <35,3 mmol/mol and ≤±8,5 % for HbA1c concentrations ≥35,3 mmol/mol. Number of results (n) = 100. An account of the number of samples is given in section 6.1.

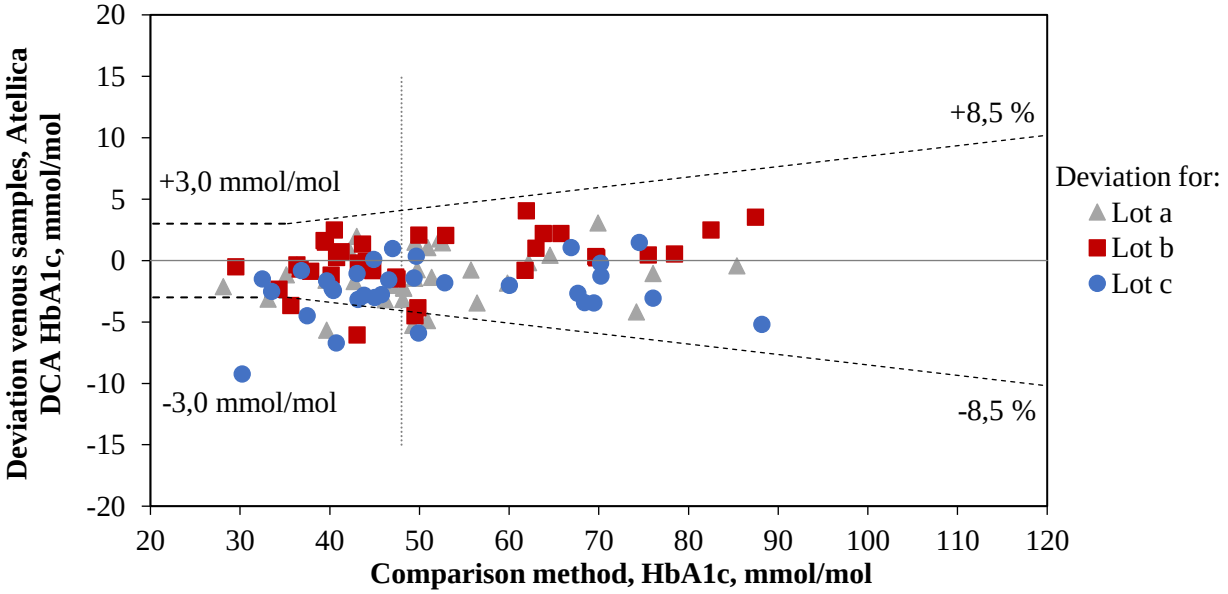

Figure 4. Accuracy of HbA1c results on the Atellica DCA HbA1c System achieved by experienced laboratory personnel at a hospital laboratory. The x-axis represents the mean HbA1c result of the comparison method. The y-axis represents the HbA1c deviation in mmol/mol of the first venous sample measurement on the Atellica DCA HbA1c System from the mean result of the corresponding sample of the comparison method. The vertical line at 48 mmol/mol HbA1c illustrates the diagnostic threshold value for diabetes. The different lots of reagent cartridges are illustrated with the symbols ▲ (Lot a), ■ (lot b) and ● (lot c). Stippled lines represent the allowable deviation limits of ≤±3,0 mmol/mol for HbA1c concentrations <35,3 mmol/mol and ≤±8,5 % for HbA1c concentrations ≥35,3 mmol/mol. Number of results (n) = 100. An account of the number of samples is given in section 6.1.

Discussion
As shown in Figure 3, the capillary HbA1c results from the Atellica DCA HbA1c System tend to be lower than the comparison method at all concentrations. As shown in Figure 4, the venous HbA1c results from the Atellica DCA HbA1c system tend to be lower than the comparison method at lower concentrations, but otherwise similar levels. These results are consistent with the calculated bias. There is no apparent lot-to-lot difference. For capillary samples 88 of 100 results were within the limits for allowable deviation, and for venous samples 89 of 100 results were within the limits for allowable deviation, corresponding to 88 % and 89 %, respectively, within the limits.

Conclusion
When used by experienced laboratory personnel at the hospital laboratory the APS for accuracy for capillary and venous samples was not fulfilled.

6.4. Analytical performance of the Atellica DCA HbA1c System achieved by health care professionals in primary health care

The results below reflect the analytical performance of the Atellica DCA HbA1c System when used by health care professionals in PHCCs. The results may deviate from the results achieved by experienced laboratory professionals.

6.4.1. Internal analytical quality control

All results, but one, from the internal analytical quality control (Atellica DCA Analyzer HbA1c Controls) two levels, were within the allowable control limits (data not shown) at PHCC1. The internal quality control result outside the limit (level 1) was considered a statistical outlier according to the criterion promoted by Burnett [14] and excluded from the calculation of reproducibility. The total reproducibility (CV) achieved with the internal analytical quality control samples on the two Atellica DCA HbA1c Systems placed in PHCC1 was 6,2 % for level 1 (n=27) and 4,7 % for level 2 (n=26). The reproducibility for each Atellica DCA HbA1c System was 5,3 % and 6,3 %, respectively, for level 1 (n=14 and 13) and 3,1 % and 5,5 %, respectively, for level 2 (n=13 and 13). Raw data is attached for the requesting company only, see attachment 8.

All results from the internal analytical quality control (Atellica DCA Analyzer HbA1c Controls), two levels, were within the allowable control limits (data not shown) at PHCC2. The total reproducibility (CV) achieved with the internal analytical quality control samples on the two Atellica DCA HbA1c Systems placed in PHCC2 was 5,5 % for level 1 (n=11) and 4,0 % for level 2 (n=10). The reproducibility for the Atellica DCA HbA1c Systems separately is not presented due to too few data (n <8). Raw data is attached for the requesting company only, see attachment 8.

6.4.2. The precision of the Atellica DCA HbA1c System

Measurements were performed with two capillary samples from each participant on the Atellica DCA HbA1c System (instruments SMS3937 PHCC1 and SMS3943 PHCC2), and duplicate measurements from each venous sample were performed on the Atellica DCA HbA1c System (instruments SMS3941 PHCC1 and SMS3942 PHCC2). The results were checked visually to meet the imposed condition for using formula 1 in attachment 4. There were no systematic differences pointed out between the paired measurements (data not shown).

The precision is presented as repeatability (CV). The CV with a 90 % CI is shown in table 9 and 10. The results were sorted and divided into three concentration intervals according to the mean of the results of the Atellica DCA HbA1c System. Raw data is attached for the requesting company only, see attachment 9.

Table 9. Repeatability (CV) of the Atellica DCA HbA1c System for HbA1c measured in capillary samples. Results achieved by health care professionals in PHCCs.

Place	Interval, mmol/mol	n	Excluded results (statistical outliers)	Mean value HbA1c, mmol/mol	CV (90 % CI), %	APS (≤3,0 %) fulfilled
	<39	10	0	36,1	6,0 (4,4 – 9,9)	No
PHCC1	39 – 59	25	0	48,6	2,2 (1,8 – 2,9)	Yes
	>59	11	0	65,7	1,9 (1,4 – 3,0)	Yes
	<39	5*	0	36,3		
PHCC2	39 – 59	28	0	45,7	3,4 (2,8 – 4,3)	Most likely not
	>59	6*	0	76,4		

An account of the number of samples is given in section 6.1.
*n<8; CV not reported due to high degree of uncertainty in the estimated CV.

Table 10. Repeatability (CV) of the Atellica DCA HbA1c System for HbA1c measured in venous samples. Results achieved by health care professionals in PHCCs.

Place	Interval, mmol/mol	n	Excluded results (statistical outliers)	Mean value HbA1c, mmol/mol	CV (90 % CI), %	APS (≤3,0 %) fulfilled
	<39	6*	0	37,1		
PHCC1	39 – 59	24	0	49,1	2,5 (2,1 – 3,4)	Most likely
	>59	14	0	67,5	2,9 (2,2 – 4,4)	Most likely
	<39	4*	0	36,9		
PHCC2	39 – 59	29	0	47,1	2,3 (1,9 – 2,9)	Yes
	>59	7*	0	87,9		

An account of the number of samples is given in section 6.1.
*n<8; CV not reported due to high degree of uncertainty in the estimated CV.

Discussion

The CV achieved by health care professionals at the PHCCs was between 1,9 and 6,0 % for capillary samples and between 2,3 and 2,9 % for venous samples. For capillary samples, the repeatability was statistically significant below the APS in both the mid- and high interval, but statistically significant above the APS at the lowest interval at PHCC1. The repeatability at the mid-interval for capillary samples at PHCC2 was above the APS, but not statistically significant above. For venous samples, the repeatability at the mid- and high intervals for venous samples at

PHCC1 was below the APS, but not statistically significant below, while the repeatability was statistically significant below the APS in the mid-interval at PHCC2. The rest of the data is not presented due to too few samples, which lead to high uncertainties with wide CIs.

Conclusion
When used by health care professionals at the PHCCs the APS for repeatability (CV ≤3,0 %) was fulfilled at HbA1c intervals <39 and 39–59 mmol/mol, but not fulfilled at HbA1c interval <39 mmol/mol for capillary samples at PHCC1. The APS was most likely not fulfilled at HbA1c interval 39–59 mmol/mol for capillary samples at PHCC2. The APS was most likely fulfilled at HbA1c levels 39–59 and >59 mmol/mol for venous samples at PHCC1. The APS was fulfilled for venous samples at PHCC2 at HbA1c interval 39–59 mmol/mol.

6.4.3. The bias of the Atellica DCA HbA1c System

The mean deviation (bias) of the results from the Atellica DCA HbA1c System from the comparison method results was calculated. The bias is presented with a 95 % CI in table 11 and 12. The results were sorted and divided into three concentration levels according to the mean results of the comparison method. Raw data is attached for the requesting company only, see attachment 5 and 9.

Table 11. Bias of the Atellica DCA HbA1c System for HbA1c measured in capillary samples. Results achieved by health care professionals in PHCCs.

Place	Interval, mmol/mol	n	Excluded results (statistical outliers)	Mean value Comparison method, HbA1c, mmol/mol	Mean value Atellica DCA, HbA1c, mmol/mol	Bias (95 % CI), mmol/mol	Bias, %
	<39	5	0	36,8	35,9	-0,9 ((-3,2) – (+1,3))	-2,5
PHCC1	39 – 59	32	0	48,2	46,0	-2,1 ((-2,9) – (-1,3))	-4,4
	>59	14	0	68,6	65,8	-2,8 ((-4,7) – (-0,9))	-4,1
	<39	3	0	35,3	35,2	-0,2 ((-3,6) – (+3,2))	-0,5
PHCC2	39 – 59	29	0	46,5	45,1	-1,5 ((-2,1) – (-0,8))	-3,1
	>59	7	0	84,0	83,6	-0,4 ((-7,1) – (+6,4))	-0,5

An account of the number of samples is given in section 6.1.

Table 12. Bias of the Atellica DCA HbA1c System for HbA1c measured in venous samples. Results achieved by health care professionals in PHCCs.

Place	Interval, mmol/mol	n*	Excluded results (statistical outliers)	Mean value Comparison method, HbA1c, mmol/mol	Mean value Atellica DCA, HbA1c, mmol/mol	Bias (95 % CI), mmol/mol	Bias, %
	<39	5	0	36,8	37,2	0,4 ((-2,2) – (+3,0))	1,0
PHCC1	39 – 59	33	1**	48,2	48,7	0,6 ((-1,8) – (+2,9))	1,2
	>59	14	0	68,6	68,5	-0,1 ((-1,6) – (+1,3))	-0,2
	<39	3	0	35,3	36,3	1,0 ((-2,1) – (+4,1))	2,8
PHCC2	39 – 59	29	0	46,5	46,7	0,2 ((-0,5) – (+0,8))	0,4
	>59	7	0	84,0	87,9	3,9 ((-1,1) – (+8,9))	4,6

*The given number of results (n) were counted before the exclusion of statistical outliers. Mean and bias were calculated after the exclusion of statistical outliers. An account of the number of samples is given in section 6.1.
**ID 305 was a statistical outlier according to Burnett's model [14] in the calculation of bias and therefore excluded.

Discussion
The bias achieved by health care professional at the PHCCs was between -4,4 and -0,5 % for capillary samples and between -0,2 and +4,6 % for venous samples. A significant difference could be seen between the methods for capillary samples when examining the intervals with the most results. There was no significant difference between the methods for venous samples.

6.4.4. The accuracy of the Atellica DCA HbA1c System

To evaluate the accuracy of HbA1c results on the Atellica DCA HbA1c System, the agreement between the Atellica DCA HbA1c System and the comparison method is illustrated in difference plots (figure 5 and 6). The limits for the allowable deviation according to the APS (≤±3,0 mmol/mol for HbA1c concentrations <35,3 mmol/mol and ≤±8,5 % for HbA1c concentrations ≥35,3 mmol/mol), are shown with stippled lines. The first capillary and venous measurement, respectively, from the Atellica DCA HbA1c System are included in the plot. The plot illustrates both random and systematic errors, reflecting the total measuring error in the Atellica DCA HbA1c System results. Raw data is attached for the requesting company only, see attachment 5 and 9.

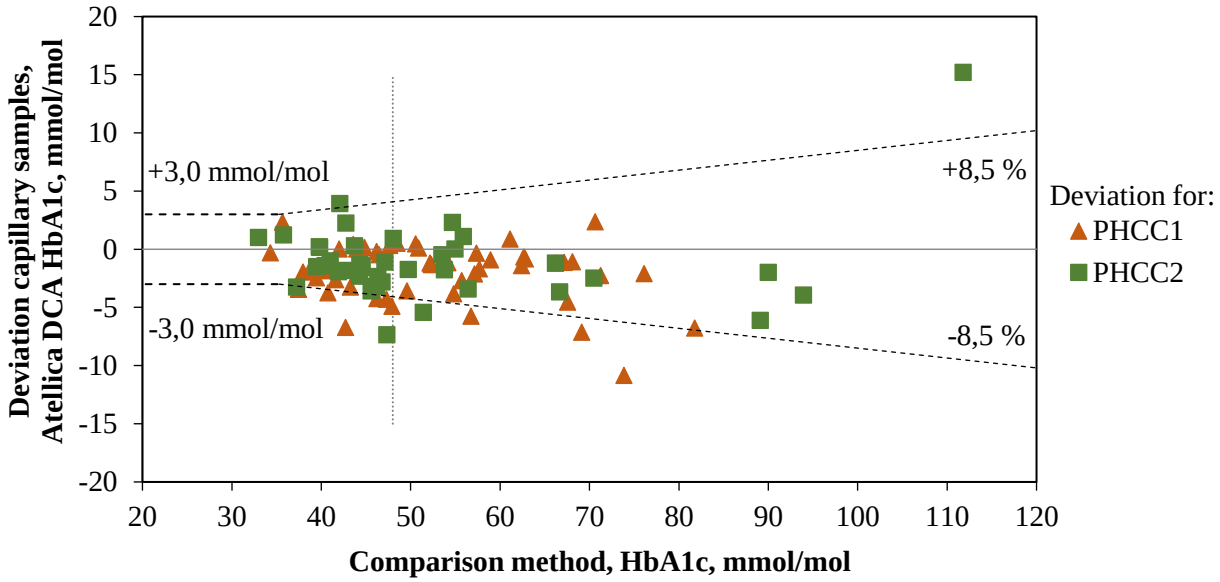

Figure 5. Accuracy of HbA1c results on the Atellica DCA HbA1c System achieved by health care professionals in PHCCs. The x-axis represents the mean HbA1c result of the comparison method. The y-axis represents the HbA1c deviation in mmol/mol of the first capillary sample measurement on the Atellica DCA HbA1c System from the mean result of the corresponding sample of the comparison method. The vertical line at 48 mmol/mol HbA1c illustrates the diagnostic threshold value for diabetes. The different PHCCs are illustrated with the symbols ▲ (PHCC1) and ■ (PHCC2). Stippled lines represent the allowable deviation limits of ≤±3,0 mmol/mol for HbA1c concentrations <35,3 mmol/mol and ≤±8,5 % for HbA1c concentrations ≥35,3 mmol/mol. Number of results (n) = 90. An account of the number of samples is given in section 6.1.

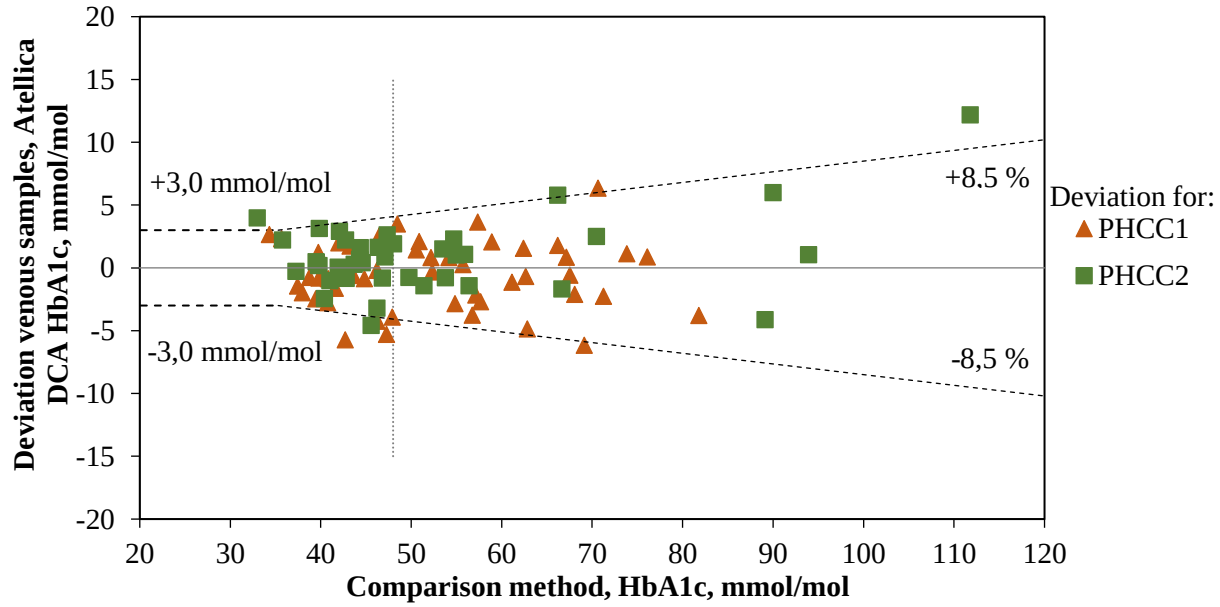

Figure 6. Accuracy of HbA1c results on the Atellica DCA HbA1c System achieved by health care professionals in PHCCs. The x-axis represents the mean HbA1c result of the comparison method. The y-axis represents the HbA1c deviation in mmol/mol of the first venous sample measurement on the Atellica DCA HbA1c System from the mean result of the corresponding sample of the comparison method. The vertical line at 48 mmol/mol HbA1c illustrates the diagnostic threshold value for diabetes. The different PHCCs are illustrated with the symbols ▲ (PHCC1) and ■ (PHCC2). Stippled lines represent the allowable deviation limits of ≤±3,0 mmol/mol for HbA1c concentrations <35,3 mmol/mol and ≤±8,5 % for HbA1c concentrations ≥35,3 mmol/mol. Number of results (n) = 89. An account of the number of samples is given in section 6.1.

Discussion

As shown in figure 5, the HbA1c results of capillary samples from the Atellica DCA HbA1c System tend to be lower than the comparison method, regardless of concentration level. The results from venous samples measured on the Atellica DCS HbA1c System is more consistent with the comparison method (figure 6). These results are in agreement with the calculated bias. For capillary samples 76 of 90 results were within the limits for allowable deviation, and for venous samples 80 of 89 results were within the limits for allowable deviation, corresponding to 84 % and 90 %, respectively, within the limits.

Conclusion

When measurements were performed by health care professionals in PHCCs the APS for accuracy for capillary and venous samples was not fulfilled.

6.5. Evaluation of user-friendliness

6.5.1. Questionnaire to the evaluators

The most important response regarding user-friendliness comes from the intended users themselves. Health care professionals in PHCCs often emphasise other aspects than those pointed out by more extensively trained laboratory personnel.

At the end of the evaluation period, the intended users, i.e., health care professionals and laboratory personnel, filled in a questionnaire about the user-friendliness of the measuring system. SKUP has prepared detailed instructions for this.

The questionnaire is divided into four subareas:

Table A) Rating of ease of operation. Is the measuring system easy to handle?
Table B) Rating of the information in the manual and the insert
Table C) Rating of time factors
Table D) Rating of analytical quality control

The intended users filled in table A and B. SKUP filled in table C and D, and topics marked with grey colour in table A and B. The information in table C is derived from information material from the manufacturer.

In the tables, the first column shows what is up for consideration. The second column in table A and B shows the rating by the users at the evaluation sites. The rest of the columns show the rating options. The overall ratings from all the evaluating sites are marked in coloured and bold text.

The total rating is an overall assessment by SKUP of the described property, and not necessarily the arithmetic mean of the rating in the rows. Consequently, a single poor rating can justify an overall poor rating if this property seriously influences the user-friendliness of the measuring system.

Unsatisfactory and intermediate ratings are marked with a number and explained below the tables. The intermediate category covers neutral ratings assessed as neither good nor bad.

An assessment of the user-friendliness is subjective, and the topics in the questionnaire may be emphasised differently by different users. The assessment can therefore vary between different persons and between the countries. This is discussed and taken into account in the overall assessment of the user-friendliness.

Comment
In this evaluation, the user-friendliness was assessed by:
Two BLSs and one assistant nurse in the hospital laboratory.
Two assistant nurses in PHCC1.
Three assistant nurses in PHCC2.

Table A. Rating of ease of operation.

Topic	Rating	Rating	Rating	Rating	Option
To prepare the test / instrument	S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
To prepare the sample	S, S, U[1]	Satisfactory	Intermediate	Unsatisfactory	No opinion
Application of specimen	S, S, U[2]	Satisfactory	Intermediate	Unsatisfactory	No opinion
Specimen volume	S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Number of procedure step	S, S, I[3]	Satisfactory	Intermediate	Unsatisfactory	No opinion
Instrument / test design	S, S, I[4]	Satisfactory	Intermediate	Unsatisfactory	No opinion
Reading of the test result	S, S, S	Easy	Intermediate	Difficult	No opinion
Sources of errors	S, U[5], N	Satisfactory	Intermediate	Unsatisfactory	No opinion
Cleaning / Maintenance	S, N[6], N	Satisfactory	Intermediate	Unsatisfactory	No opinion
Hygiene, when using the test	S, S, N	Satisfactory	Intermediate	Unsatisfactory	No opinion
Size and weight of system	S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Storage conditions for tests,		+15 to +30°C	+2 to +8°C[7]	–20°C	
Storage conditions for tests, opened package		+15 to +30°C or disposable	+2 to +8°C	–20°C	
Environmental aspects: waste handling (test cartridges)		No precautions[8]	Sorted waste[8]	Special precautions	
Intended users		Health care personnel or patients	Laboratory experienced personnel[9]	Biomedical laboratory scientists	
Total rating by SKUP		Satisfactory			

[1]Impractical to have the test cartridge and the capillary holder in separate packages, especially on busy days. It was easy to forget to bring both to the testing station, and it was easy to miss opening both before putting on gloves.
[2]It was difficult (resistance) to insert the capillary holder into the test cartridge; difficult to know if the holder were all the way down or inserted incorrectly. In addition, it was difficult to remove the foil, especially in finding the balance in pulling it off without harming the equipment.
[3]Difficult to evaluate the number of steps since there were so many samples per patient, it felt like more steps than it probably was. *Note from SKUP; intermediate rating not included in total rating.*
[4]The analyser itself had a nice design including size and it was convenient to have a connected printer. However, the test cartridge and capillary holder were not well designed. Handling required removal of foil on both parts, and it was difficult to insert the capillary holder into the cartridge.

[5] Error codes were not saved in memory, if you accidentally clicked it away it could not be retrieved again. It would also be good to have larger font on the error code. *Note from SKUP; error codes can be recalled from the memory of the system. This is described in the advanced user guide.*
[6]No opinion since cleaning was not necessary during the evaluation period.
[7]The reagent cartridges can be stored at room temperature for up to eight weeks, for longer storage they need to be kept in refrigerator.
[8]The used reagent cartridges contains human blood and should be disposed of according to local guidelines as these can differ between sites.
[9]The intended users are both health care personnel and personnel with laboratory experience.

Additional positive comments to the ease of operation:
Nice design. Small and handy. Perfect to have a printer. Easy to learn to use.

Additional negative comments to the ease of operation:
There was quite a lot of waste. It was inconvenient and difficult to open the package of the capillary holder. The flap on the reagent cartridge foil was too small, so it was difficult to get it all off, leaving too small opening. The blood sample was not stable in the reagent cartridge for as long as the manufacturer stated (4 minutes) *(Note from SKUP; Only tested on a few duplicate capillary samples).*

Table B. Rating of the information in the user manual and insert.

Topic	Rating	Rating	Rating	Rating	Option
Table of contents/Index	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Description of preparations/pre-analytic procedure	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Description of specimen collection	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Description of measurement procedure	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Description of how to read the result	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Description of the sources of error	**S, U[1], N**	**Satisfactory**	Intermediate	**Unsatisfactory**	**No opinion**
Description of troubleshooting	**S, U[2], N**	**Satisfactory**	Intermediate	**Unsatisfactory**	**No opinion**
Readability/Clarity of presentation	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
General impression	**S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Description of measurement principle		**Satisfactory**	Intermediate	Unsatisfactory	
Available insert in Danish, Norwegian, Swedish		**Satisfactory**	Intermediate	Unsatisfactory	
Total rating by SKUP		**Satisfactory**			

[1]Some error codes were not presented in the manual.
[2]Miss complete explanations of what to do for some error codes.

Table C. Rating of time factors (rated by SKUP).

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

Table D. Rating of analytical quality control (rated by SKUP).

Topic	Rating	Rating	Rating
Reading of the internal quality control	**Satisfactory**	Intermediate	Unsatisfactory
Usefulness of the internal quality control	**Satisfactory**	Intermediate	Unsatisfactory
Total rating by SKUP	**Satisfactory**		

6.5.2. Assessment of the user-friendliness

Assessment of the ease of operation (table A)

The ease of operation was in total assessed as satisfactory although there were some intermediate and unsatisfactory ratings. The motivations for the lower ratings mainly concerned the design, and hence handling, of the reagent cartridge and capillary holder; both required removal of foil, which could be challenging. In addition, it was commented that it was hard to insert the capillary holder into the reagent cartridge. There were very few error codes during the evaluation, only 1,2 % of the measurements failed due to technical errors.

Assessment of the information in the user manual/insert/quick guide (table B)

The user manual was assessed as satisfactory although pointed out that not all error codes were presented.

Assessment of time factors (table C)

The time factors were assessed as satisfactory.

Assessment of analytical quality control (table D)
The analytical quality control was assessed as satisfactory as it was easy to read results, it was patient-like and the handling procedure was the same as for patient samples, in addition the colour made it easy to see that the capillary was filled. The only drawback was that the reproducibility of the internal analytical quality control material was slightly higher than the repeatability of patient samples, which is not optimal for revealing failing analytical quality.

Conclusion
In all, the user-friendliness of the Atellica DCA HbA1c System as well as the manual, time factors and analytical quality control were rated as satisfactory. The performance specification for user-friendliness was fulfilled.

7. References

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13. Tellinghuisen J. Inverse vs. classical calibration for small data sets. Fresenius J. Anal. Chem. 2000; 368 (6): 585 – 588.

Attachments

1. Facts about the Atellica DCA HbA1c System
2. Information about manufacturer, retailers and marketing
3. Product specifications for this evaluation, Atellica DCA HbA1c System
4. Statistical expressions and calculations
5. Raw data HbA1c, results from the comparison method
6. Raw data HbA1c, internal analytical quality control results, Atellica DCA HbA1c System, at the hospital laboratory
7. Raw data HbA1c, Atellica DCA HbA1c System results, at the hospital laboratory
8. Raw data HbA1c, internal analytical quality control results, Atellica DCA HbA1c System, in primary health care
9. Raw data HbA1c, Atellica DCA HbA1c System results, in primary health care
10. Letter from Siemens Healthineers

Attachments with raw data are included only in the copy to Siemens Healthineers.

Facts about the Atellica DCA HbA1c System

This form is filled in by Siemens Healthineers.

Table 1. Basic facts

Name of the measurement system:	Atellica® DCA Analyzer
Dimensions and weight:	Width: 151 mm Depth: 260 mm Height: 287 mm Weight: 2.16 kg
Components of the measurement system:	Analyzer, test cartridges, capillary holders
Measurand:	HbA1c
Sample material:	Whole blood, capillary or venous
Sample volume:	1 µL
Measuring principle:	Immunoassay turbidimetric
Traceability:	IFCC/NGSP
Calibration:	Calibration is included on a 2D barcode located directly on the cartridge. No operator intervention is required. The assay is directly calibrated to IFCC, and traceable to NGSP.
Measuring range:	20 – 130 mmol/mmol
Haematocrit range:	Hb concentrations in the range of 7.0 – 20.0 g/dL Estimated haematocrit range 21 – 60 %
Measurement time:	Approximately 5 minutes
Operating conditions:	15 to 32°C (10-90% RH non-condensing)
Electrical power supply:	The system will be capable of operating from a main electrical supply (100-240 V AC, 47/63 Hz). The handheld display has a rechargeable battery, which is charged when docked to the analyser.
Recommended regular maintenance:	No recommended regular maintenance Air filter must be changed as needed (analyser will alert the user as the filter gets clogged)
Package contents:	Analyzer module, tablet display, power cord, printed operators' guide in local languages, optical test cartridge
Necessary equipment not included in the package:	Lancet for fingerstick

Table 2. Post analytical traceability

Is input of patient identification possible?	Yes, via touchscreen or barcode reader
Is input of operator identification possible?	Yes, via touchscreen or barcode reader
Can the instrument be connected to a bar-code reader?	Yes; tablet display includes a barcode reader
Can the instrument be connected to a printer?	Yes; Bluetooth or network printer
What can be printed?	Patient results, QC results, configuration report
Can the instrument be connected to a PC?	Yes
Can the instrument communicate with LIS (Laboratory Information System)? If yes, is the communication bidirectional?	Yes; bidirectional communication
What is the storage capacity of the instrument and what is stored in the instrument?	Patient results: 10 000 QC results: 5 000 Operator IDs: 10 000
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:	Atellica® DCA HbA1c reagent cartridges
Stability in unopened sealed vial:	2 years from date of manufacture
Stability in opened vial:	The HbA1c Reagent cartridge must be used within one hour after opening the foil pouch
Package contents:	10 HbA1c reagent cartridges, capillary holders, printed IFU

Table 4. Quality control

Electronic self check:	The rotational position of the motor and cartridge can be determined from the signals received from the Home/Index sensor. An LED range check is done as well as a heater check.
Recommended control materials and bottle volume:	Atellica® DCA Analyzer HbA1c Controls; 1 mL per vial
Stability in unopened sealed vial:	30 months from date of manufacture
Stability in opened vial:	30 days at 2 - 8°C
Package contents:	2x normal control level; 2x abnormal control level, control card with scannable ranges

Information about manufacturer, retailers and marketing

This form is filled in by Siemens Healthineers.

Table 1. Marketing information

Manufacturer:	Siemens Healthcare Diagnostics, Inc. 511 Benedict Avenue Tarrytown, NY 10591 USA
Retailers in Scandinavia:	Denmark: Timik ApS Sivlandsvænget 27B, st. th. 5260 Odense S Denmark Norway: Timik AS Brynsveien 18 C 0667 Oslo Norway Sweden: Timik AB Hammarbacken 4A 191 49 Sollentuna Sweden
In which countries is the system marketed:	Globally ☒ Scandinavia ☐ Europe ☐
Date for start of marketing the system in Scandinavia:	April 2024
Date for CE-marking:	October 2020
In which Scandinavian languages is the manual available:	Swedish, Norwegian, Danish

Product specifications for this evaluation, Atellica DCA HbA1c System

Atellica DCA Analyzer serial numbers

Serial no Module	Serial no Display	Used by
SMS0069	SMS220340080	Hospital laboratory
SMS3940	SMS202960011	
SMS3937	SMS220340028	PHCC1
SMS3941	SMS220340123	
SMS3942	SMS223320156	PHCC2
SMS3943	SMS223320161	

Atellica DCA HbA1c Reagent Cartridges

Lot no	Alias	Expiry date	Used by
7920924	Lot a	2026-09-17	All evaluation sites
7240424	Lot b	2026-04-25	All evaluation sites
7060324	Lot c	2026-03-11	All evaluation sites

Atellica DCA Analyzer HbA1c Controls

Control	Lot no	Allowable range, mmol/mol	Expiry date	Used by
Level 1	4308	32 – 45	2026-10-31	All evaluation sites
Level 2		69 – 89		

Statistical expressions and calculations

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

Statistical terms and expressions

The definitions in this section come from the International Vocabulary of Metrology - Basic and general concepts and associated terms; 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. Accuracy is descriptive in general terms (good, poor e.g.). A measurement is said to be more accurate when it offers a smaller measurement error. Accuracy can be illustrated in a difference plot.

a. International vocabulary of metrology – Basic and general concepts and associated terms, VIM, 3rd edition, JCGM 200;2012. www.bipm.org

Statistical calculations

Statistical outliers

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

Calculation of imprecision

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

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

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 cons tant 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. A paired t-test is used with the mean values of the duplicate results on the comparison method and the mean values of the duplicate results on the evaluated method. The mean difference is shown with a 95 % confidence interval.

Assessment of accuracy

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

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e. 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 HbA1c, results from the comparison method

Raw data are included only in the copy to Siemens Healthineers.

Raw data HbA1c, internal analytical quality control results, Atellica DCA HbA1c System, at the hospital laboratory

Raw data are included only in the copy to Siemens Healthineers.

Raw data HbA1c, Atellica DCA HbA1c System results, at the hospital laboratory

Raw data are included only in the copy to Siemens Healthineers.

Raw data HbA1c, internal analytical quality control results, Atellica DCA HbA1c System, in primary health care

Raw data are included only in the copy to Siemens Healthineers.

Raw data HbA1c, Atellica DCA HbA1c System results, in primary health care

Raw data are included only in the copy to Siemens Healthineers.

Letter from Siemens Healthineers

Dear Sir/Madam, 19 May 2025

RE: Comments on SKUP evaluation of HbA1c assay on the Atellica DCA Analyzer

Thank you for the evaluation and assessment of the Atellica DCA Analyzer. We appreciate the thoroughness of your planning, execution, analysis and presentation of material. We also thank the busy professionals who had taken time to execute the protocol and the patients who participated in this evaluation.

We have respectfully added a few observations.

User Friendliness – Rating of Ease of Operation

We acknowledge there is room for improvement and some of these are already being addressed in upcoming updates while we will consider other inputs in future revisions.

- Footnote # 5 - Error codes were not saved in the memory: The error codes are in fact saved and can be accessed from the error log. Instructions are provided in the advanced user guide. During the evaluation, we did not receive this question and were not able to help. We request that this not be categorized as 'Unsatisfactory'.
- Footnote # 8 - Used cartridges contain human blood and should be disposed of according to local guidelines: This is true for all diagnostics products using human blood samples for measurement.
- Under additional negative comments, it has been highlighted that blood sample was not stable in the reagent cartridge for 4 minutes. The capillary tube is heparinized and this stability has been characterized by us when the capillary holder is properly inserted in the reagent cartridge.

Analytical Performance

Repeatability:

Performance shows less than 3% CV in clinically important interval of 39-59 mmol/mol supported by strength of data in that interval. Data in the other intervals are inconclusive.

We maintain IFCC and NGSP certification. We will continue to monitor accuracy performance.

Sincerely,

Rajesh Krishnan

Global Product Lead, Primary Care

Siemens Healthcare Diagnostics Inc.
Point of Care Diagnostics
www.siemens-healthineers.com/point-of-care-testing

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