DiaSpect Hemoglobin T System

A system for measurement of haemoglobin

manufactured by DiaSpect Medical GmbH

Report from the evaluation SKUP/2013/96

organised by SKUP at the request of

ANL-produkter AB, Sweden

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The report was written by SKUP, April 2013. For more details about SKUP, see attachment 1.
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Attachments 7 and 9 with raw data are included only in the report to *ANL-produkter AB, Sweden.*

1. Summary

Background
DiaSpect Hemoglobin T System is intended for the determination of haemoglobin concentration in whole blood. The instrument uses a photometric method with compensation for turbidity. No reagents are involved. The system, manufactured by DiaSpect Medical GmbH, has been launched in many countries including Scandinavia.

The aim of the evaluation was to
- examine the imprecision of haemoglobin results measured with DiaSpect Hemoglobin T
- compare capillary and venous results in a hospital laboratory and in two primary health care centres with an established hospital laboratory method for haemoglobin (Sysmex XE-5000)
- evaluate the control materials for DiaSpect Hemoglobin T
- evaluate the user-friendliness of DiaSpect Hemoglobin T at two primary health care centres

Materials and methods
Four DiaSpect Hemoglobin T instruments and three lots of cuvettes were used. 102 patients from a hospital and 82 patients visiting two primary health care centres were included for capillary sampling. 222 venous samples and three levels of control material were also analysed.

Results
Capillary samples: At two primary health care centres the imprecision (CV) was between 3,0 and 3,9%. The results were inconclusive on fulfilling the quality goal ≤3,0%; most likely the quality goal was not fulfilled. 72% of the sample results fulfilled the quality specifications of < ±5,0% from the comparison method. When used in the hospital laboratory, the quality goal was 'fulfilled' for high, 'inconclusive most likely fulfilled' for medium and 'not fulfilled' for the low haemoglobin concentrations.
Venous samples: The quality goal for imprecision was fulfilled both when the instrument was used in the hospital laboratory (CV = 0,7%) and in the primary health care centres (CV = 0,7% and 0,9%). With samples stored less than 24 h the bias from the comparison method was −2,0% in the hospital laboratory and -0,4 to +1,8% at the two primary health care centres. In the hospital laboratory 95%, and at the primary care centres 98%, of the results from samples stored less than 24 hours were within the quality specifications for allowable deviation.
The control materials at three concentration levels showed a CV ≤1,0%.
User-friendliness: The manual, the time factors and the quality control were rated as satisfactory by both primary health care centres. One centre also rated 'operation' as satisfactory. The other centre was less satisfied because they had to use blood drop number four and five for the measurement.
Technical errors: There were in total three technical errors of 963 results.

Conclusion
Capillary samples: The quality specifications for imprecision was fulfilled for the capillary samples with high concentrations, but not for low concentrations in the hospital laboratory. In the primary health care the quality specifications for imprecision was most likely not fulfilled.
Venous samples: Results from samples stored less than 24 hours fulfilled the quality goals for precision and trueness, both in the hospital laboratory and in the two primary health care centres.
The control materials can be used as indicators of the function of the instruments.
User-friendliness: One primary health care centre was satisfied with the instrument. The other did not normally discard the first three drops of blood and found it difficult to use blood drop number four.
The percent of technical errors: was less than 1,0%.

Comments from the manufacturer
None

2. Abbreviations

C-NPU	Committee on Nomenclature, Properties and Units
CI	Confidence Interval
CV	Coefficient of Variation
DAK-E	Danish Quality Unit of General Practice
DANAK	Danish Accreditation and Metrology Fund
DEKS	Danish Institute of External Quality Assurance for Laboratories in Health Care
EQA	External Quality Assessment
Equalis	External quality assurance in laboratory medicine in Sweden
GP	General Practitioner
IFCC	The International Federation of Clinical Chemistry and Laboratory Medicine
ICSH	The International Council for Standardization in Hematology
IUPAC	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

SKUP has performed several evaluations of instruments designed for haemoglobin measurements, (see attachment 11). The quality goals in this evaluation, and in the previous evaluations, are based on biological variation [1] and medical requirements. General practitioners in Denmark want to be able to detect a haemoglobin decrease from 7,0 mmol/L to 6,2 mmol/L (112 g/L to 98,2 g/L or 11,2 g/dL to 9,82 g/dL) [2, 3].

The National Danish Committee for General Practice Laboratory Testing appointed by the National Ministry of Health has specified the demands to analytical quality [2,3] for haemoglobin for instruments used in primary health care. The Danish goals also include demands to the comparison laboratory:

Primary health care	Bias ≤2%, CV ≤3%
The comparison method	Bias ≤1%, CV ≤2%

Allowable deviation ≤ ± [| bias | + 1,65 x CV], where bias ≤2%, CV ≤3% ~ <±5%

3.2. Evaluation of user-friendliness

The evaluation of user-friendliness is carried out by asking the evaluating persons (end-users) to fill in a questionnaire.

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

- Rating of information in manual and insert
- Rating of time factors at 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, respectively.

3.3. Principles for the assessments

3.3.1. *Assessment of the analytical quality*

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

Precision

The distinction between the ratings, and the assessment of precision according to the quality goal, are shown in table 1.

Table 1. The rating of precision

Distinction between the ratings	Assessment according to the quality goal
The CV is lower than the quality goal	The quality goal is fulfilled
The CV is lower than the quality goal (not statistically significant)	Data is inconclusive on fulfilling the quality goal. Most likely the quality goal is fulfilled
The CV is higher than the quality goal (not statistically significant)	Data is inconclusive on fulfilling the quality goal. Most likely the quality goal is not fulfilled
The CV is higher than the quality goal	The quality goal is not fulfilled

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

3.3.2. *Assessment of the user-friendliness*
The user-friendliness is assessed according to the answers and comments given in the questionnaire (see section 5.5.). For each question, the user must choose between three given ratings, as for instance satisfactory, intermediate or unsatisfactory. The response from the users is reviewed and summed up. To achieve the overall rating ”satisfactory”, the tested equipment must reach the total rating of “satisfactory” in all four sub-areas of characteristics mentioned in section 5.5.

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

3.4. SKUP´s quality goals in this evaluation
SKUP will assess the results from the evaluation of DiaSpect Hemoglobin T against the following quality goals:

	Quality goals	**Required percentage of results within the allowable deviations**
Repeatability CV	≤3,0%	
Accuracy (Allowable deviation)	≤±5,0%	≥95%
Fraction of technical errors	≤2%	
User-friendliness	Satisfactory	

4. Materials and methods

4.1. Definition of haemoglobin

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” [4]. In the database the recommended name is given for the measurand, together with which unit the result should be reported in.

Table2. Name, code and unit for haemoglobin according to C-NPU

NPU code	Full name of test according to NPU	Short name	Unit*
NPU02319	B – Haemoglobin(Fe); stofk.	Haemoglobin	mmol/L

*g/L, g/dL and mmol/L can be displayed. Internally in the instrument the factor 0,6205 is used for conversion of g/L to mmol/L. Conversion factor 1,61 from mmol/L to g/dL. Conversion factor 16,1 from mmol/L to g/L.

In this report the term “haemoglobin” will be used for this measurand. The unit used in the report is mmol/L.

4.2. The evaluated DiaSpect Hemoglobin T System

The DiaSpect Hemoglobin T system consists of the DiaSpect Hemoglobin T analyzer and the DiaSpect Hemoglobin Cuvettes (Figure 1). The system uses no reagents. The DiaSpect instrument utilizes a broad-spectrum, multichromatic sensor which measures the absorbance of whole blood over a wide spectral range simultaneously. From these data the total haemoglobin concentration is calculated. The measuring system of DiaSpect Hemoglobin T is unique and patented [5]. The DiaSpect Hemoglobin T is a single analyte instrument.
The haemoglobin level is determined and appears in the display after a measuring time of about 1 second.
Technical data from the manufacturer is shown in table 3 and in attachment 2. For sampling information, see also attachment 2.

Figure 1 The DiaSpect Hemoglobin T is shown with a filled cuvette inserted.

Table 3 Technical data DiaSpect Hemoglobin T

Operating temperature	15–35°C
Sample material	Capillary or venous whole blood
Blood volume	<10 µl
Measurement range	0–15,9 mmol/L (0–25,5 g/dl, 0–255 g/L)
Wavelength	450 nm to 750 nm
Measuring time:	1–2 sec
Storage capacity	1 result
Power supply	3,6 V integrated lithium-ion batteries
Power adapter Input	100–240 V AC, 50–60 Hz
Duration of use	40 h for a fully charged battery and continuous use
Dimensions and Weight	W, H and D = 14, 7 and 21,5 cm, weight 500 g

For name of the manufacturer and suppliers in the Scandinavian countries, see attachment 3.

4.3. The selected comparison method

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

4.3.1. *The selected comparison method in this evaluation*

The selected comparison method in this evaluation of DiaSpect Hemoglobin T was the Sysmex haemoglobin method on the instrument Sysmex XE-5000, at the Department of Clinical Biochemistry in Hillerød, Denmark, hereafter called "the comparison method" (table 4). The method is accredited by The Danish Accreditation and Metrology Fund, DANAK. Two different instruments were used.

Table 4. Information about the comparison method Sysmex XE-5000, Haemoglobin

Analytical principle	Photometry
Haemoglobin Mol weight	M_r: 16.115 (monomer)
Reproducibility	1% (calculated from internal quality control, value 8 mmol/L)
Traceability, calibrator	ICSH-reference method for haemoglobin. ICSH-standard 1995 [6]
Detection limit	0,1 mmol/l
Measuring interval	0,0–15,5 mmol/l
Internal quality control	E-Check level 1+2+3 (Sysmex Denmark)
External quality control	Haematology program HÆM (DEKS; 3041 DK)

The analytical quality goal for the comparison method in the Department of Clinical Biochemistry in Hillerød has is CV% <1,4% and Bias <1,8%.

4.4. The evaluation

4.4.1. *Planning of the evaluation*

Background for the evaluation

The DiaSpect Hemoglobin T manufactured by DiaSpect Medical GmbH in Germany has been launched in many countries including Scandinavia. The instrument uses a new technology for the measurement of haemoglobin.

Inquiry about an evaluation

ANL-produkter AB, Sweden, applied for a SKUP evaluation of DiaSpect Hemoglobin T in the autumn 2011. SKUP in Denmark accepted to carry out this evaluation.

Protocol and contract

The protocol for the evaluation was approved in March 2012. ANL-produkter AB, Sweden and SKUP in Denmark signed the contract the 8th of June 2012.

Preparations and training program

On the 8th of June 2012 Stine Weber and Esther Jensen, SKUP, were trained for approximately one hour by Liselott Thapper, ANL-produkter AB, Sweden and Solveig Eckerbom, DiaSpect. The biomedical laboratory scientist Britta Otte, Farum, and nurse Birgitte Nielsen, Helsinge, also were trained one hour each. Esther Jensen, SKUP taught both of them the logistic procedures in the evaluation.

The DiaSpect Hemoglobin T instruments arrived in Hillerød Hospital the 7th of June 2012. The practical work with the evaluation was carried out between June and September 2012.

4.4.2. *Evaluation sites and persons involved*

Evaluation under standardised conditions took place at the Department of Clinical Biochemistry, Hillerød Hospital. All participants in the evaluation are presented in table 5.

Table 5 Persons responsible for various parts of the evaluation

Name	Title	Organisation	Responsibility
Liselott Thapper	Business Area Manager	ANL-produkter AB, Sweden	Ordered the evaluation
Solveig Eckerbom	Scientific Affairs Manager	DiaSpect Medical	Developer
Björn Gillberg	CEO	ANL-produkter AB, Sweden	Signed the contract
Stine Weber	Chemist	SKUP	Practical work with the evaluation
Esther Jensen	Physician	SKUP	Author of the report
Birgitte Nielsen	Nurse	Lægerne i Vestergade, Helsinge	Practical work with the evaluation
Britta Otte	Biomedical laboratory scientist	Jens Juhl Otte, Farum	Practical work with the evaluation
Doris Nellemann	Biomedical laboratory scientist	Department of Clinical Biochemistry, Hillerød Hospital	Responsible for the comparison method

4.4.3. *The evaluation model*

The evaluation consists of two parallel parts. One part of the evaluation was carried out under standardised and optimal conditions by laboratory educated personnel in a hospital laboratory using about 100 capillary and 100 venous samples from 100 individuals. The evaluation in the hospital laboratory lasted over at least 20 days and 3 lots of test cuvettes were used. This part of the evaluation documents the quality of the system under conditions optimal for achieving good analytical quality.

The second part of the evaluation was performed in two primary health care centres by proposed end-users. The centres each include at least 40 patients. From each patient two capillary samples were measured and a venous sample was drawn for the comparison method. At least one of the centres should not have a biomedical laboratory scientist employed.

4.4.4. *The aim of the evaluation was to*

In the hospital laboratory:

- examine the analytical quality of haemoglobin results measured with DiaSpect Hemoglobin T under standardised and optimal conditions with about 100 venous and 100 capillary patient samples
- compare capillary and venous results measured with DiaSpect Hemoglobin T with an established hospital laboratory method for haemoglobin
- evaluate the control materials for DiaSpect Hemoglobin T
- evaluate the user-friendliness

In each of the primary health care centres:

- examine the analytical quality of haemoglobin results measured with DiaSpect Hemoglobin T in two primary health care centres with at least 40 capillary patient samples
- compare capillary and venous results measured with DiaSpect Hemoglobin T in a hospital laboratory and in two primary health care centres with an established hospital laboratory method for haemoglobin
- evaluate the user-friendliness of DiaSpect Hemoglobin T at two primary health care centres

4.4.5. *The evaluation procedure in the hospital laboratory under standardised and optimal conditions*

Internal analytical quality control

Three levels of the internal quality control samples for the DiaSpect Hemoglobin T (DiaSpect Control HB) were measured in duplicate each evaluation day during the evaluation period.

Recruitment of patients

Outpatients coming to the hospital laboratory to have their haemoglobin measured routinely were invited to participate in the hospital laboratory evaluation. Participation was voluntary, and verbal consent was considered sufficient. Each patient was included only once.

Collection of samples

At least 100 capillary and 100 venous EDTA patient samples were included in the evaluation. The request of concentration levels of haemoglobin results are given in table 6.

Table 6. Requirements on the distribution of haemoglobin concentration in the samples

Proportion of samples demanded	**5%**	**20%**	**40%**	**5%**
Haemoglobin (mmol/L) range	<5,58	5,65 – 7,45	7,46 – 10,09	>10,10
Haemoglobin (g/dL) range	<9,0	9,1 – 12,0	12,1 – 16,1	>16,2
Haemoglobin (g/L) range	<90	91 – 120	121 – 161	>162

Conversion factor 1,61 from mmol/L to g/dL. Conversion factor 16,1 from mmol/L to g/L

Handling of samples and measurements, DiaSpect Hemoglobin T

All individuals had two capillary samples and a venous EDTA sample drawn.

The two capillary samples were collected from one finger prick and measured on DiaSpect Hemoglobin T. The first three drops of blood were removed, one cuvette was filled from the 4th drop, and the other cuvette was filled from the 5th drop. The capillary samples were measured on DiaSpect Hemoglobin T within 15 seconds.

The venous sample for DiaSpect Hemoglobin T and the comparison method was collected using a four mL K2-EDTA tube from Greiner. The sample was stored at room temperature and analysed in duplicate within two hours from collection on both DiaSpect Hemoglobin T and the comparison method.

Four measurements (two capillary and two venous) per patient were performed using one lot number of test cuvettes and one DiaSpect Hemoglobin T instrument.

Three lot numbers of DiaSpect Hemoglobin T cuvettes were used in this evaluation.
Analysing on the comparison method
Two instruments were used for the comparison method. All venous samples were analysed on both Sysmex instruments, resulting in duplicate results from all patients. The time from blood sampling to analysis of the last measurement was three hours or less.

Recording of results
All results were registered consecutively on a registration form prepared by SKUP. All recorded data from the instruments were stored. All analysing data, mistakes and errors were reported. All results were signed by the person performing the practical work.

Evaluation of user-friendliness
The evaluators of DiaSpect Hemoglobin T evaluated the user-friendliness after the practical work by means of the user-friendliness questionnaire worked out by SKUP.

4.4.6. *Evaluation procedure in primary health care*

Internal analytical quality control
Three levels of DiaSpect Control HB were measured each evaluation day.

Recruitment of patients and sample collection
Two primary health care centres were enrolling patients. At least 40 patients per centre, coming to have their haemoglobin measured, were invited to participate in the evaluation. Participation was voluntary and verbal consent was considered to be sufficient. Each patient was included only once. There were no demands to the haemoglobin concentrations of the results.

Handling of samples and measurements, DiaSpect Hemoglobin T
From each patient two capillary samples were collected from one finger prick and measured on DiaSpect Hemoglobin T. The first three drops of blood were removed, one cuvette was filled from the 4^{th} drop, and the other cuvette (same lot) was filled from the 5^{th} drop. Two lots of test cuvettes were used in each primary care centre. The capillary samples for the evaluation were measured on DiaSpect Hemoglobin T within 15 seconds.
A venous sample for the comparison method was collected from each patient using a K2-EDTA tube from Greiner. The samples were stored at room temperature, send to Hillerød Hospital and analysed in duplicate with both DiaSpect Hemoglobin T and the comparison method.

During the evaluation it was decided to include venous samples with varying storage time (storage <24 hours and 24-72 hours) in the evaluation. Most of these samples were given to the primary health care centres from the hospital laboratory.

Recording of results
All results were registered consecutively on a registration form prepared by SKUP. All recorded data from the instruments were stored. All analysing data, mistakes and errors were reported. All results were signed by the person performing the practical work.

Evaluation of user-friendliness
The evaluators of DiaSpect Hemoglobin T evaluated the user-friendliness after the practical work by means of the user-friendliness questionnaire worked out by SKUP.

5. Results and discussion

Statistical expressions and calculations used by SKUP are shown in attachment 4.
Formula 2 is used for repeatability in this evaluation.

5.1. Number of samples

Hospital
In the hospital laboratory evaluation, 101 individuals participated with capillary and venous measurements on DiaSpect Hemoglobin T. All measurements were made in duplicates, in total four results for each patient.
In addition one venous sample (24-72 hours old) with a low haemoglobin of 2,7 mmol/L was measured on DiaSpect Hemoglobin T (2,5 mmol/L on the comparison method) . This measurement is included in the calculations for precision, but not for trueness and accuracy.

Primary health care centres
In the primary health care evaluation, one centre recruited 40 patients for duplicate capillary measurements, the other 42 patients. 40 venous patient samples were included for the evaluation in both centres. The venous patient samples >24 hours and some of the samples <24 hours originate from the hospital laboratory and were given to the primary health care centres.

5.1.1. *Excluded and missing results*

In the hospital laboratory evaluation, two capillary sample results were excluded as outliers according to the rules of Burnett, because of large differences between duplicate results:
No. 21: DiaSpect capillary sample results: 8,0 and 9,4 mmol/L. The two venous DiaSpect results were both 9,1 mmol/L and the two Sysmex results were 9,3 and 9,4 mmol/L.
No. 34: DiaSpect capillary sample results: 7,9 and 9,0 mmol/L. The two venous DiaSpect results were 9,1 and 9,0 mmol/L and the Sysmex results were both 9,2 mmol/L.

5.1.2. *Failed measurements*

In the hospital laboratory:
No. 74: error: light source too dark in venous sample. Test repeated without comments.
No. 76: error: light source too dark in venous sample. Test repeated without comments.
No. 82: drawer blocked. Test repeated without comments.

In the primary health care:
No 231: failed measurement due to difficulties obtaining the 5th drop of blood.
Results from samples collected on one given day in primary health care centre 1 were not included in the evaluation because the closing mechanism on instrument 2 became remarkably slower. The break-down did not give any error messages, but the haemoglobin values clearly dropped. The control results from this day are also removed. Instrument 3, the backup instrument, was used for the rest of the evaluation.

The total number of technical errors in the hospital laboratory and the primary health care centres was three of 963; therefore the fraction of errors was less than 1,0%.

Conclusion
DiaSpect Hemoglobin T had three technical errors and did fulfil the quality goal of a maximum of 2% waste due to technical errors.

5.2. Analytical quality of the selected comparison method

5.2.1. *The trueness of the comparison method*
The external quality controls from DEKS demonstrated in the period May to September 2012 a bias on the Sysmex instruments of +0,04% (−1,02 to +0,82%).

Conclusion
The goal for bias <1,8% for the comparison method was fulfilled.

5.2.2. *Internal quality control*
The Sysmex CBC L2 controls from the manufacturer Sysmex are measured six times a year, four times during the evaluation. The deviation from the mean concentrations (7,5 to 7,7 mmol/L) in both Sysmex instruments were about +0,9% and the CV was about 1,0%. Other internal quality control samples were run daily with CV <1% (data not reported).

Conclusion
The control results were within the allowable intervals. The CV achieved with the control material was <1,4%, and the analytical quality goal for the precision of the comparison method was fulfilled.

5.2.3. *The precision of the comparison method*
The calculated CV values are measures of imprecision. However, the 'repeatability' is not just 'repeatability' because the duplicate measurements always originate from two different Sysmex instruments.

Table 7. Repeatability of Sysmex, calculated using venous whole blood patient samples results from duplicate measurements originating from two Sysmex instruments.

Level	Comparison method interval (mmol/L)	n	Excluded results	Comparison method mean (mmol/L)	CV (95% CI) (%)
Low	2,50 — 7,90	34	0	6,74	0,6 (0,5 — 0,8)
Medium	7,95 — 8,70	36	0	8,37	0,6 (0,4 — 0,7)
High	8,75 — 11,35	32	0	9,45	0,6 (0,5 — 0,8)
All	2,50 — 11,35	102	0	8,14	0,6 (0,5 — 0,7)

Conclusion
As seen in table 7 the two comparison instrument measure very identically. A 'repeatability' of 0,6% of the combination of the two Sysmex instruments fulfils the goal for CV < 1,0% for the comparison method.

5.3. Analytical quality of DiaSpect Hemoglobin T in a hospital laboratory

5.3.1. *External quality control*

During the hospital laboratory evaluation one external control material from DEKS was tested. The target value for the control was 7,668 mmol/L. (The procedure 'to set target' of the controls is described in the SKUP report no 47). DiaSpect Hemoglobin T measured 7,9 and 7,8 mmol/L. The bias was +2,3%.

Discussion and conclusion

SKUP has no bias goal; the Danish quality goal for haemoglobin is a bias ≤2%.
Genuine control materials are always more than three days old when it was analysed. The manufacturer claims that the DiaSpect haemoglobin concentration "can increase up to 3% between day 1 and day 5 after collection of a venous sample.". Given these informations, the result is acceptable.

5.3.2. *Internal quality control*

The three levels of DiaSpect Control HB were measured in duplicate each evaluation day.
The reproducibility of DiaSpect Hemoglobin T achieved with the control materials is shown in table 8 and raw data is shown in attachment 6.

Table 8. Reproducibility of DiaSpect Hemoglobin T with control materials in the hospital laboratory

DiaSpect Control HB	n	Mean haemoglobin (mmol/L)	Reproducibility CV (%)
Low	42	4,9	0,6
Normal	42	7,8	0,6
High	40	9,9	0,5

Discussion

All results were within the control range. The CV achieved with the control materials during 24 days was 0,6%, 0,6% and 0,5% for the DiaSpect Control HB, low, normal and high control material, respectively

Conclusion

The quality goal for imprecision, a CV less than 3,0%, was achieved with the three control materials.

5.3.3. *Comparison of the 1st and 2nd measurement*

Two capillary and a venous sample was drawn from each person for duplicate measurements on DiaSpect Hemoglobin T. The results were checked to meet the assumption for using formula 2 in attachment 4. There were no systematic differences pointed out between the paired measurements (data not shown).

5.3.4. *The precision of DiaSpect Hemoglobin T*

Repeatability under standardised and optimal measuring conditions in a hospital laboratory was obtained with capillary (table 9) and venous whole blood samples (table 10) measured in duplicates on the DiaSpect Hemoglobin T. The raw data are not shown. Repeatability was calculated for three subgroups: low, medium and high haemoglobin values. The three groups were chosen according to their concentration with the comparison method (mean of two Sysmex instruments).

Table 9. Repeatability of DiaSpect Hemoglobin T with capillary patient samples in the hospital laboratory

Level	Comparison method mean (interval) mmol/L	n	Excluded results	DiaSpect Hemoglobin T mean mmol/L	CV% (95% CI)
Low	6,9 (5,00 — 7,90)	33	0	6,7	4,2 (3,5 — 5,7)
Medium	8,4 (7,95 — 8,70)	36	0	8,1	2,3 (1,9 — 3,1)
High	9,5 (8,75 — 11,35)	32*	2	9,1	2,0 (1,6 — 2,7)
All	8,2 (5,00 — 11,35)	101*	2	7,9	3,0 (2,7 — 3,6)

The given numbers of results (n) are counted before the exclusion of outliers. Mean and CV are calculated after the exclusions.* No. 21 and no. 34 were outliers according to Burnett.

Table 10. Repeatability of DiaSpect Hemoglobin T with venous patient samples in the hospital laboratory

Level	Comparison method mean (interval) mmol/L	n	Excluded results	DiaSpect Hemoglobin T mean mmol/L	CV% (95% CI)
Low	6,7 (2,50 — 7,90)	34	0	6,7	0,6 (0,5 — 0,9)
Medium	8,4 (7,95 — 8,70)	36	0	8,2	0,9 (0,7 — 1,2)
High	9,5 (8,75 — 11,35)	32	0	9,2	0,6 (0,5 — 0,8)
All	8,2 (2,50 — 11,35)	102	0	8,0	0,7 (0,7 — 0,9)

Discussion

The calculated CV values are measures of repeatability during 23 days. Three lots of cuvettes were used for analysing on two DiaSpect Hemoglobin T instruments. For the haemoglobin concentration intervals low, medium, and high the repeatability CV was 4,2%, 2,3%, and 2,0% with capillary samples and 0,6%, 0,9%, and 0,6% with venous samples, respectively. The repeatability CV% for the low Haemoglobin capillary sample results (≤7,9 mmol/L haemoglobin) did not fulfil the quality goal (<3,0%). For medium Haemoglobin concentration results the CV% is lower than the quality goal, but not statistically significant. Data is therefore inconclusive on fulfilling the quality goal, though most likely the quality goal is fulfilled. For high concentrations of haemoglobin (≥9,2 mmol/L) the CV% fulfils the quality goal of <3,0%.

For the venous sample results the repeatability CV% fulfilled the goal of <3,0% for all concentrations.
It is known from for example previous SKUP evaluations, attachment 11, that capillary samples compared with venous samples have higher CV%. The major reason for the inaccuracy in a capillary result occurs as preanalytical errors in the capillary puncture, rather than when the sample is sucked up into the cuvette.
In table 9 the preanalytical factors are measured as part of the CV% in the duplicates, and in table 10 the preanalytical issue is minimised.

Conclusion
The DiaSpect Hemoglobin T instrument can obtain a CV% <3,0% with capillary samples (Haemoglobin concentrations >8,7 mmol/L), and with venous samples with concentrations between 2,5 and 11,35 mmol/L and with DiaSpect Control HB. The low haemoglobin capillary sample results (≤7,9 mmol/L haemoglobin) did not fulfil the quality goal. For medium haemoglobin concentration results the CV% is lower than the quality goal, but not statistically significant. Data for the medium haemoglobin concentration level is therefore inconclusive on fulfilling the quality goal, though most likely the quality goal is fulfilled.

5.3.5. *The trueness of DiaSpect Hemoglobin T*
The mean deviation of DiaSpect Hemoglobin T from the comparison method (bias) was calculated from the results achieved by a chemist and a physician with three lots of cuvettes on two DiaSpect Hemoglobin T instruments. The results are sorted and divided into three haemoglobin levels according to the mean results on the comparison method. The trueness of DiaSpect Hemoglobin T is shown in table 11 and 12.

Table 11. Trueness of DiaSpect Hemoglobin T with capillary patient samples in the hospital laboratory

Level	Comparison method mean (interval) mmol/L	n	Excluded results	DiaSpect Hemoglobin T mean mmol/L	Bias (95% CI) %
Low	6,9 (5,00 — 7,90)	33	0	6,7	–3,5 ((–5,4) – (–1,5))
Medium	8,4 (7,95 — 8,70)	36	0	8,1	–3,2 ((–4,3) – (–2,0))
High	9,5 (8,75 — 11,35)	32*	2	9,1	–3,8 ((–5,0) – (–2,7))
All	8,2 (5,00 — 11,35)	101*	2	7,9	–3,5 ((–4,3) – (–2,6))

The given numbers of results (n) are counted before the exclusion of outliers. Mean and bias are calculated after the exclusions. *No. 21 and No. 34 were outliers.

Table 12. Trueness of DiaSpect Hemoglobin T with venous patient samples in the hospital laboratory

Level	Comparison method mean (interval) mmol/L	n	Excluded results	DiaSpect Hemoglobin T mean mmol/L	Bias (95% CI) %
Low	6,9 (2,50 — 7,90)	34*	1	6,7	–1,4 ((–2,3) – (–0,5))
Medium	8,4 (7,95 — 8,70)	36	0	8,2	–1,9 ((–2,4) – (–1,5))
High	9,5 (8,75 — 11,35)	32	0	9,2	–2,6 ((–3,0) – (–2,1))
All	8,2 (2,50 — 11,35)	102*	1	8,1	–2,0 ((–2,3) – (–1,6))

The given numbers of results (n) are counted before the exclusion of outliers. Mean and bias are calculated after the exclusions. *No. 102 (2,5 mmol/L with the comparison method) had been stored >24 hours and were excluded.

Discussion

The haemoglobin measurements on DiaSpect Hemoglobin T gave systematic lower results than the comparison method. The deviation from the comparison method was –3,5% for capillary samples and –2,0% for the venous samples. The deviations of the results were not dependent on haemoglobin concentration/haematocrit for neither capillary nor venous samples (figure 2-4). The deviation is statistically significant for both capillary and venous samples. There was no separate goal for bias in the evaluation. In case of a high bias the quality goals for accuracy are more difficult to achieve.

In the literature some studies have demonstrated, that capillary samples have higher haemoglobin concentration than the corresponding venous blood samples [7-10]. In SKUP evaluation no. 47 the capillary results were also significantly lower than the corresponding venous whole blood results. We have no explanation for the lower concentrations in the capillary samples found in this evaluation or the previous evaluation.

5.3.6. *The accuracy of DiaSpect Hemoglobin T*

To evaluate the accuracy of the results on DiaSpect Hemoglobin T, the agreement between DiaSpect Hemoglobin T and the comparison method is illustrated in two accuracy plots. The plots show the deviation of single measurement results on DiaSpect Hemoglobin T from the comparison method, and give a picture of both random and systematic deviation, reflecting the total measuring error on DiaSpect Hemoglobin T. The accuracy is demonstrated for the first measurement of the paired results, only.

The accuracy of DiaSpect Hemoglobin T, with capillary samples and three lots of test cuvettes, under standardised and optimal measuring conditions is shown in figure 2. The accuracy of DiaSpect Hemoglobin T, as measured with venous samples is shown in figure 3. The results are shown in the unit g/L in figure Ia and Ib (attachment 7).

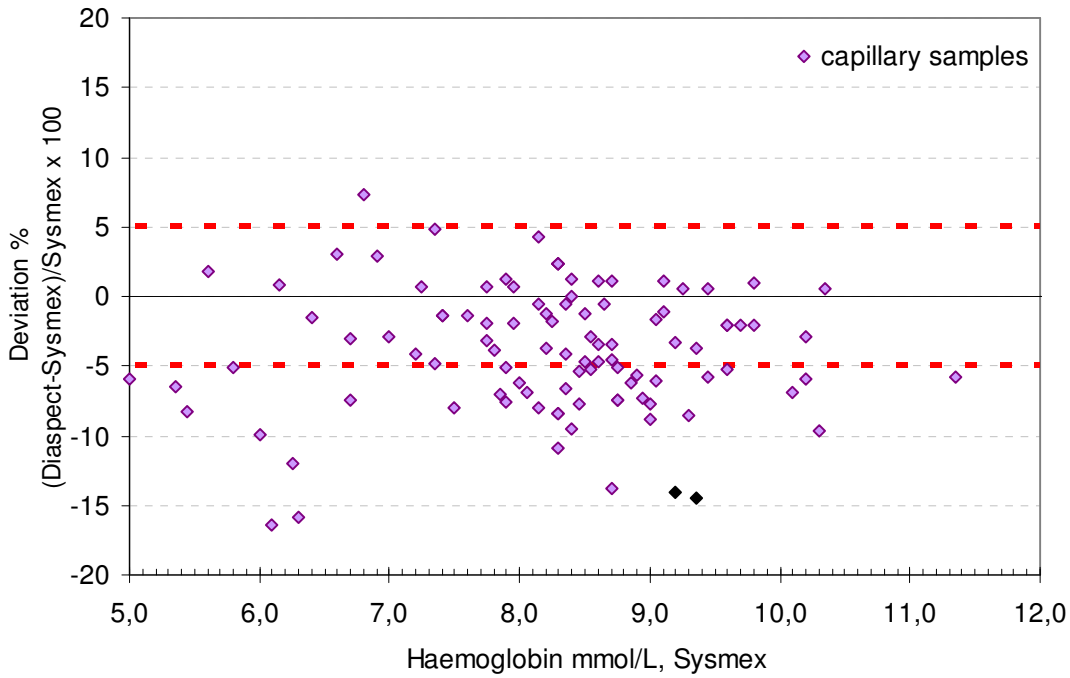

Figure 2. Accuracy. DiaSpect Hemoglobin T (three lots of cuvettes) with capillary samples in the hospital laboratory under standardised and optimal measuring conditions. The x-axis represents the mean result on the comparison method. The y-axis shows the difference between the first measurement on DiaSpect Hemoglobin T and the mean result of the comparison method. The stippled lines represent the limits for allowable deviation ±5,0%. ID 21 and 34, the statistical outliers from the calculation of repeatability in the high group, are represented with closed black symbols, n = 101.

The supplier was contacted after 20 samples because the deviation from comparison method was larger than expected for capillary but not for venous samples (figure 3). The company replied that it was a matter of sampling: getting a good flow of blood, based on good circulation, warm and relaxed hands, easily getting a large drop of blood that should flow freely. The sampling conditions were considered as optimal as possible; however, the last 60 patients had a deeper skin penetration than the first 30. This did not, however, change the deviation from comparison method for the capillary samples.

The accuracy plot is based on the first measurements of each duplicate. In the calculation of precision, two pairs of duplicate values were pointed out as outliers in the high concentration level. The two outliers appear in figure 2, marked with black symbols. Two results in the low concentration range deviate even more from the comparison method, but were not segregated as outliers in the calculation of precision. This only means that the agreement within the duplicate measurements must be better for these two results than for the two outlier results.

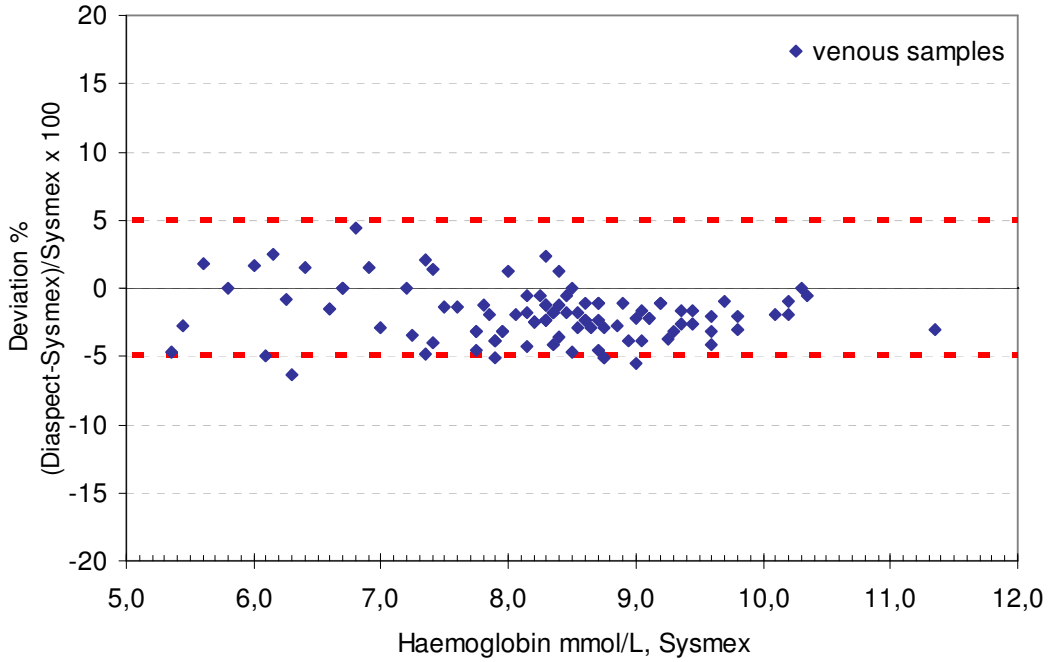

Figure 3. Accuracy. DiaSpect Hemoglobin T (three lots of cuvettes) in the hospital laboratory under standardised and optimal measuring conditions. The x-axis represents the mean result on the comparison method. The y-axis shows the difference between the first measurement on DiaSpect Hemoglobin T and the mean result of the comparison method. The stippled lines represent limits for allowable deviation ±5,0%, n = 101.

Discussion

Figure 2 demonstrates that the DiaSpect Hemoglobin T results with capillary samples do not fulfil the quality goal of a deviation less than 5,0% from the comparison method under optimal and standardised conditions as only 57 out of 101 results (57%) were within the limits in the Department of Clinical Biochemistry.

Figure 3 confirms that the DiaSpect Hemoglobin T results with venous samples show good agreement with the comparison method. 96 out of 101 results (95,0%) were inside the limits for the allowable deviation of ±5,0 %. The DiaSpect Hemoglobin T results are slightly lower than the comparison method at all concentrations. The small deviation has no clinical importance.

The results obtained with venous samples at DiaSpect Hemoglobin T under standardised and optimal conditions in the Department of Clinical Biochemistry fulfil the quality goals.

Conclusion

Sampling is of great importance in capillary haemoglobin measurements. The haemoglobin concentration in capillary samples is sensitive to how well blood flow and how much you squeeze the finger during sampling. The results can be too high or too low as a result of this. The preanalytical error is present not only for DiaSpect Hemoglobin T, but for all instruments using capillary samples for measuring B-Haemoglobin (attachment 11). The uncertainty does not disqualify capillary samples for B-Haemoglobin, but the user of the result has to consider whether the capillary analytical quality is good enough in the clinical situation.

In average the capillary sample results were approximately 1,5% lower than the venous results when using DiaSpect Hemoglobin T.

5.3.7. *Variation between three lots of cuvettes – Influence of lot numbers*
For each patient the same lot of cuvettes was used for the venous samples and for the capillary samples. The venous results fulfilled the quality goal with a deviation <5,0% in at least 95% of the results. Significant lot variation of clinical importance cannot be present.

5.4. Analytical quality of DiaSpect Hemoglobin T in the primary health care centres

5.4.1. *Internal quality control*
The three levels of DiaSpect Control HB were measured each evaluation day.
The reproducibility of DiaSpect Hemoglobin T is shown in table 13 and raw data are shown in attachment 8.

Table 13. Internal quality control in the two primary care centres

	Primary health care centre 1			**Primary health care centre 2**		
Control	low	medium	high	low	medium	high
n	25	25	25	12	12	12
Mean	4,90	7,78	9,88	4,95	7,78	9,89
CV%	0,4	0,5	0,7	1,0	0,7	0,8

Discussion
The mean values for the control materials were 4,9 – 7,8 – 9,9 mmol/L for the low, the medium and the high control, and they were the same in both primary health care centres as in the hospital laboratory. The CV achieved with the DiaSpect Control HB controls were ≤1,0%.
Instrument 2 in primary health care centre 1 broke, causing lower haemoglobin values. The mean values for the controls from the days were lower than before (4,80 – 7,47 – 9,45 mmol/L). The control revealed the drop in accuracy

Conclusion
The quality goal for imprecision, a CV of less than 3,0% was achieved with all three control materials. The control material reflected that one DiaSpect Hemoglobin T instrument began to measure too low during the evaluation (attachment 8).

5.4.2. *The precision of DiaSpect Hemoglobin T*
Repeatability in the two primary health care centres was obtained with capillary (table 14) and venous whole blood samples (table 15) measured in duplicates on the DiaSpect Hemoglobin T. Repeatability was calculated for two subgroups: the lowest and the highest haemoglobin concentrations. The two groups were chosen according to their concentration with the comparison method.

Table 14. Repeatability of DiaSpect Hemoglobin T with capillary patient samples in the primary health care centres

Level	Comparison method mean (interval) mmol/L	n	Excluded results	DiaSpect Hemoglobin T mean mmol/L	CV% (95% CI)
Primary health care centre 1					
Low	8,2 (6,30 — 8,75)	20*	1	7,9	3,0 (2,3 — 4,4)
High	9,4 (8,80 — 10,70)	20	0	9,2	3,9 (3,0 — 5,7)
All	8,8 (6,3 — 10,70)	40*	1	8,6	3,5 (2,9 — 4,5)
Primary health care centre 2					
Low	8,3 (7,35 — 8,70)	21	0	8,0	3,2 (2,5 — 4,6)
High	9,2 (8,75 — 11,25)	21	0	8,9	3,4 (2,6 — 4,8)
All	8,7 (7,35 — 11,25)	42	0	8,5	3,3 (2,7 — 4,2)

*The given numbers of results (n) are counted before the exclusion of outliers. Mean and CV are calculated after the exclusions. One result was not a duplicate measurement DiaSpect Hemoglobin T.

Table 15. Repeatability of DiaSpect Hemoglobin T with venous patient samples in Primary health care centres

Level	Comparison method mean (interval) mmol/L	n	Excluded results	DiaSpect Hemoglobin T mean mmol/L	CV% (95% CI)
Primary health care centre 1					
Low	6,6 (4,35 — 8,20)	20	0	6,7	0,9 (0,7 — 1,3)
High	9,0 (8,20 — 10,70)	20	0	8,9	0,6 (0,4 — 0,8)
All	7,8 (4,35 — 10,70)	40	0	7,8	0,7 (0,6 — 0,9)
Primary health care centre 2					
Low	6,4 (5,30 — 7,00)	20	0	6,7	0,9 (0,7 — 1,3)
High	8,5 (7,40 — 10,10)	20	0	8,7	0,8 (0,6 — 1,2)
All	7,6 (5,30 — 10,10)	40	0	7,8	0,9 (0,7 — 1,1)

The capillary samples in the primary health care centres were fresh. The venous samples from primary health care centre 1 were stored less than 24 hours. The venous samples from the other centre were stored both <24 hours and 24-72 hours.

Discussion
The calculated CV values are measures of repeatability. For the haemoglobin concentration intervals low and high the repeatability CV was 3,0 to 3,9% with capillary samples and 0,6 to 0,9% with venous samples. The repeatability CV% for the capillary samples is inconclusive on fulfilling the quality goal (<3,0%) in both centres. Most likely the quality goal is not fulfilled. For the venous sample results the repeatability CV% fulfilled the goal of <3,0% for all concentrations. The repeatability was independent on the storage time of the samples.
As mentioned previously, it is shown in other SKUP-evaluations (Chempaq, Biotest, Hemocontrol) that capillary samples compared with venous samples have higher CV%. The main reason of the inaccuracy in a capillary result does not arise when the sample is sucked up into the cuvette. It is a preanalytical error occurring in the capillary puncture.
Reproducibility with DiaSpect Control HB at three levels at the two primary health care centres demonstrated that the CV% was ≤1,0%.
In table 14 the pre-analytical factors are part of the CV% in the duplicates, and in the tables 13 and 15 the preanalytical issue is minimised.

Conclusion
The DiaSpect Hemoglobin T instrument can obtain a CV% ≤1,0% with venous samples, as well as with the control material from the producer. The CV% for the capillary samples was inconclusive on fulfilling the quality goal (<3,0%) in both centres. Most likely the quality goal was not fulfilled.
The reproducibility with DiaSpect Control HB in the primary health care centres is as good as the repeatability with genuine venous samples and it was seen, that the control materials did reflect the concentration of the patient sample.

5.4.3. *The trueness of DiaSpect Hemoglobin T in primary health care*
The mean deviation of DiaSpect Hemoglobin T from the comparison method (bias) was calculated from the results achieved by a nurse and a biomedical laboratory scientist with three lot of cuvettes on three DiaSpect Hemoglobin T instruments. The results were sorted and divided into two haemoglobin levels according to the mean concentration on the comparison method. The trueness of DiaSpect Hemoglobin T is shown in tables 16 and 17.

Table 16. Trueness of DiaSpect Hemoglobin T with capillary patient samples in the primary health care centres

Level	Comparison method Haemoglobin mean (interval) mmol/L	n	Excluded results	DiaSpect Hemoglobin T mean mmol/L	Bias % (95% CI)
Primary health care centre 1					
Low	8,2 (6,30 — 8,75)	20*	1	7,9	–1,1 ((–3,2) – (+1,0))
High	9,4 (8,80 — 10,70)	20	0	9,2	–1,6 ((–3,3) – (+0,1))
All	8,8 (6,30 — 10,70)	40*	1	8,6	–1,4 ((–2,6) – (+0,0))
Primary health care centre 2					
Low	8,3 (7,35 — 8,70)	21	0	8,0	–2,9 ((–4,6) – (–1,2))
High	9,2 (8,75 — 11,25)	21	0	8,9	–3,8 ((–5,3) – (–1,4))
All	8,7 (7,35 — 11,25)	42	0	8,5	–3,5 ((–4,4) – (–1,9))

*The given numbers of results (n) are counted before the exclusion of outliers. Mean and bias are calculated after the exclusions. One result was not a duplicate measurement.

Table 17. Trueness of DiaSpect Hemoglobin T with venous patient samples from the primary health care centres

Level	Comparison method Haemoglobin mean (interval) mmol/L	n	Excluded results	DiaSpect Hemoglobin T mean mmol/L	Bias % (95% CI)
Samples stored less than 24 hours, centre 1					
Low	6,5 (4,35 — 8,20)	20*	1	6,7	+1,8 ((+0,8) – (+2,8))
High	9,0 (8,20 — 10,70)	20	0	8,9	–0,4 ((–1,2) – (+0,3))
All	7,8 (4,35 — 10,70)	40*	1	7,8	no calculation
Samples stored less than 24 hours, centre 2					
Low	8,3 (7,35 — 8,60)	20	0	8,5	+0,3 ((–0,5) – (+1,1))
High	9,2 (8,70 —11,25)	20	0	9,3	+1,8 ((+1,0) – (+2,6))
All	8,8 (7,35 —11,25)	40	0	8,9	+1,0 ((+0,4) – (+1,6))
Samples stored more than 24 hours					
Low	6,5 (5,30 — 8,70)	20	0	6,7	+2,9 ((+1,7) – (+4,0))
High	8,5 (7,40 — 9,85)	20	0	8,7	+2,1 ((+1,1) – (+3,0))
All	7,6 (5,30 — 9,85)	40	0	7,8	+2,4 ((+1,7) – (+3,1))

*The given numbers of results (n) are counted before the exclusion of outliers. Mean and bias are calculated after the exclusions. One result was not a duplicate measurement with DiaSpect Hemoglobin T.

Discussion
In the hospital laboratory the DiaSpect Hemoglobin T bias was negative in all concentration intervals with both capillary and venous samples.

In the primary health care centres the capillary results on DiaSpect Hemoglobin T also had a negative bias.
For the venous results <24 hours the bias did not differ from 0 with the high concentrations in one primary health care centre and with the lowest results in the other centre, however, the bias was positive for the other two groups and for all samples stored 24-72 hours. It seems that the bias increases when the samples are stored.
The manufacturer states that samples should be measured within 72 hours, however, it is also mentioned, that DiaSpect Hemoglobin T values can increase up to +3% between day 1 and day 5 after collection of a venous sample.

This evaluation showed that it is likely that samples stored 24 to 72 increase bias with +1 to +2%. There was no separate goal for bias in the evaluation. In case of a high bias the quality goals for accuracy are more difficult to achieve.

5.4.4. *The accuracy of DiaSpect Hemoglobin T in primary health care*
The agreement between DiaSpect Hemoglobin T and the comparison method is illustrated in accuracy plots. The plots show the deviation of single measurement results on DiaSpect Hemoglobin T from the true value. This gives a picture of both random and systematic deviation, reflecting the total measuring error on DiaSpect Hemoglobin T. The accuracy is demonstrated for the first measurements of the paired results.
The accuracy of DiaSpect Hemoglobin T, with capillary samples and three lots of test cuvettes, is shown in figure 4. The accuracy of DiaSpect Hemoglobin T with venous samples and three lots of cuvettes, is shown in figure 5. The results are shown in the unit g/L in figure IIa and IIb (attachment 9).

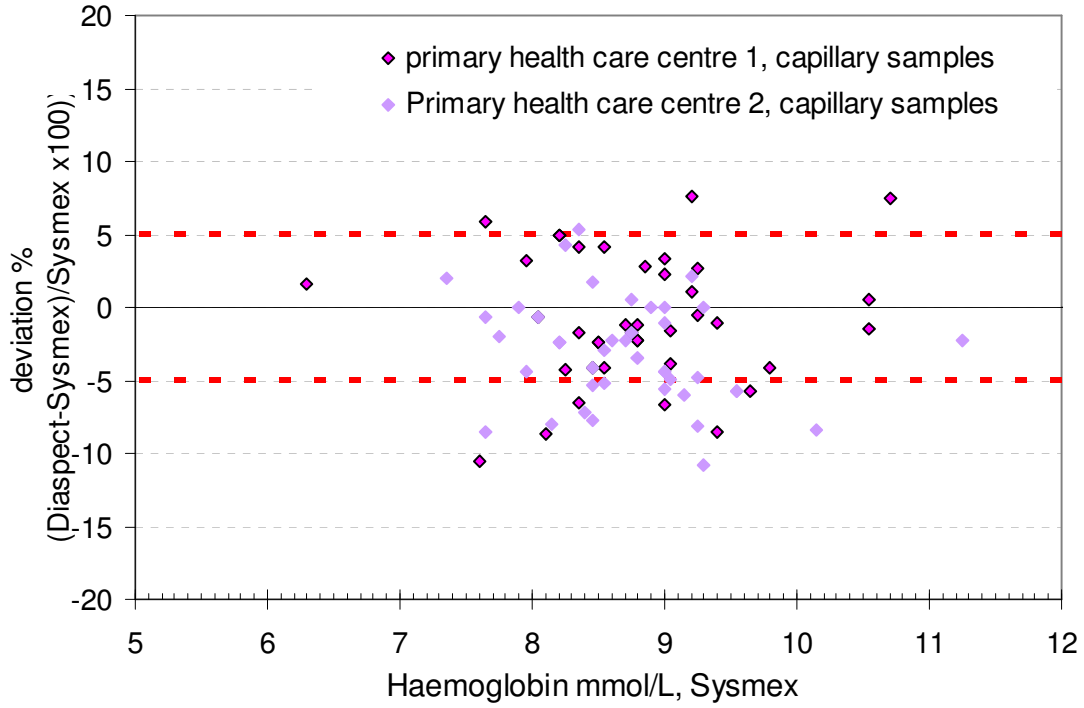

Figure 4. Accuracy. DiaSpect Hemoglobin T with capillary samples and three lots of cuvettes in two primary health care centres. The x-axis represents the mean result on the comparison method. The y-axis shows the difference between the first measurement on DiaSpect Hemoglobin T and the mean result of the comparison method. The dotted lines represent the quality goal limits of ±5,0%. N=82.

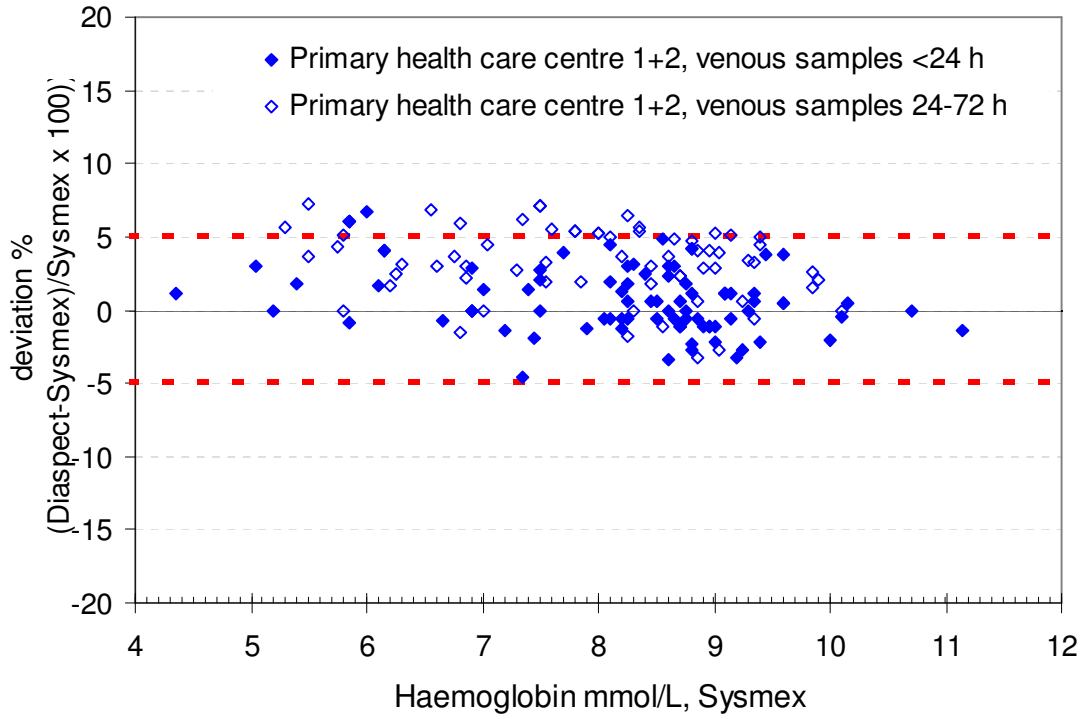

Figure 5. Accuracy. DiaSpect Hemoglobin T venous samples (three lots of cuvettes) from two primary health care centres. The x-axis represents the mean result on the comparison method. The y-axis shows the difference between the first measurement on DiaSpect Hemoglobin T and the mean result of the comparison method. The dotted lines represent the quality goal limits of ±5,0%. N=80 samples <24 h and 71 samples 24 -72 h.

Discussion

Figure 4 demonstrates that the DiaSpect Hemoglobin T results with capillary samples do not fulfil the quality goal of a deviation less than 5,0% from the comparison method in primary health care. 59 out of 82 results (72%) were inside the limits. In figure 5 73,2% of the DiaSpect Hemoglobin T results with venous samples stored 24 – 72 hours fulfil the quality goal while 19 of 71 (26,8%) of the results deviate +5,1 to +7,3%.

Venous samples stored less than 24 hours before measurement show good agreement with the comparison method. 78 out of 80 results (97,5%) were inside the limits for the allowable deviation of ±5,0%.

Conclusion

The results obtained with capillary samples in primary health care centres do not fulfil the accuracy quality goal. The preanalytical error for capillary samples is valid not only for DiaSpect Hemoglobin T, but for all instruments using capillary samples for measuring B-Haemoglobin, i.e. the results in the SKUP reports number 17, 23, 29 and 47. This does not disqualify capillary samples for B-Haemoglobin, but the user of the result has to consider whether the capillary analytical quality is good enough in the clinical situation. The results obtained with venous samples on DiaSpect Hemoglobin T in primary health care centres fulfil the quality goals when the samples were stored less than 24 hours.

5.5. Evaluation of user-friendliness

5.5.1. *Questionnaire to the evaluators*

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

At the end of the evaluation period, each user filled in a questionnaire about the user-friendliness of the instrument. The questionnaire is divided 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?

The questionnaire and the expressed opinions are presented in Table 18 to 21. The first column shows what is up for consideration. The second column shows the rating by the individual users at the evaluation sites. The third to fifth column show the rating options. Coloured frames mark the cells with the overall ratings from all evaluating sites. The last row in each table summarises the total 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 rows. 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 a nurse in one of the primary health care centres and a biomedical laboratory scientist in the other primary health care centre.

Table 18. Rating of the information in the manual / insert

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

Primary health care centre 1 wrote: have not used the manual.
Primary health care centre 2 wrote: have only used the “quick manual”.

Table 19. Rating of time factors

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

*For a primary health care centre with only one physician the stability of test, when opened need to be more than 30 days.

Table 20. Rating of quality control possibilities

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

** the stability of the control material should be more than 6 days.

Table 21. Rating of the operation facilities

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

* 'venous samples: it is not possible to draw a sample directly from the tube'. ** 'It is not easy to let the blood run to achieve blood drop number 4 and 5 for sampling. It was good it was not winter'. *** 'OK, if cuvettes and tubes for venous samples were fitting. Fine for capillary samples'. **** 'The instrument is not 'patient safely' when one has to use blood drop number 4 and 5'. Comment from DiaSpect: it is not recommended by DiaSpect or other manufacturers to fill cuvettes directly from a tube. The instructions for capillary sampling from DiaSpect are identical to instructions from other manufacturers.

5.5.2. *Assessment of the user-friendliness*

Discussion

The evaluators mentioned that the results are present very quick. The nurses in one primary health care centre were very happy with the instrument. In the other centre the biomedical laboratory scientist used another instrument for haemoglobin and would not consider DiaSpect Hemoglobin T for personal use because it was recommended to use blood drop number four. The instructions for capillary sampling from DiaSpect are identical to instructions from other manufacturers. Manufacturers recommend to wipe off blood drop no. 1-3 for capillary sampling; however, in Denmark most biomedical laboratory scientists and nurses have learn to use blood drop no. 2 for the haemoglobin analysis.

Blood drop number four is recommended – not because of needs for the instrument, but in order to optimize the preanalytical uncertainty in the capillary results. According to the manufacturer, the first three drops can give both high and low result depending on the sampling. In this evaluation capillary blood drop number 4 or 5 did not give results within ±5,0% from the comparison method. It is not known, how the results from blood drop number 1, 2 or 3 would have performed. To our knowledge, no instrument has been tested and reached the quality goal with deviations of less than ±5,0% from the comparison method results with capillary samples.

The allowed storage condition of 2,5 year, and temporarily temperatures of -30°C to +70°C were not part of the evaluation.
The results were 2-3% higher in whole blood when the whole blood had been stored 24-72 hours.

6. References

1. http://www.westgard.com/biodatabase1.htm
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10. [Precision and accuracy of the immediate determination of hemoglobin using HemoCueB Hemoglobin in urgent, surgical, and critical patients] Munoz Gomez M, Naveira Abeigon E, Romero Ruiz A, Ramirez Ramirez G. Rev Esp Anestesiol Reanim. 2003 Aug-Sep;50(7):332-9. Spanish.

Attachments

Attachment 1 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. If suppliers use the SKUP name in marketing, they have to refer to www.skup.nu and to the report code in question. For this purpose the company can use a logotype available from SKUP containing the report code.

SKUP reports are published at www.skup.nu.

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

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

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

Attachment 2 Facts about the DiaSpect Hemoglobin T System

Parts of this form are filled in by ANL / DiaSpect Medical GmbH

Table 1. Basic facts

Name of the measurement system:	DiaSpect Hemoglobin T
Dimensions and weight:	Width: 140 mm Depth: 215 mm Height: 70 mm Weight: 500 g
Components of the measurement system:	DiaSpect Hemoglobin T analyzer, DiaSpect Hemoglobin Cuvette
Measurand:	Total Hemoglobin
Sample material:	Fresh whole blood (venous or capillary)
Sample volume:	<10 uL
Measuring principle:	Photometric broad spectrum with compensation for turbidity and scattering. No reagents involved
Traceability:	HiCN / ICSH
Calibration:	Factory calibrated against international reference method, ICSH. Self check at start up and between each measurement
Measuring range:	0 – 255 g/L, 0 – 15,9 mmol/L
Linearity:	1,1 – 15,8 mmol/L
Measurement duration:	1 – 2 sec
Operating conditions:	15 – 35°C
Electrical power supply:	3,6 V integrated Li-Ion battery; Fully charged battery last for >40 hours continuous use. Power adapter input: 100 – 240 V AC, 50 – 60 Hz
Recommended regular maintenance:	Cleaning of cuvette holder (daily or when needed)
Package contents:	Delivered in transport case: DiaSpect Hemoglobin analyzer, charger, operating manual
Necessary equipment not included in the package:	DiaSpect Hemoglobin Cuvettes

Table 2. Post analytical traceability

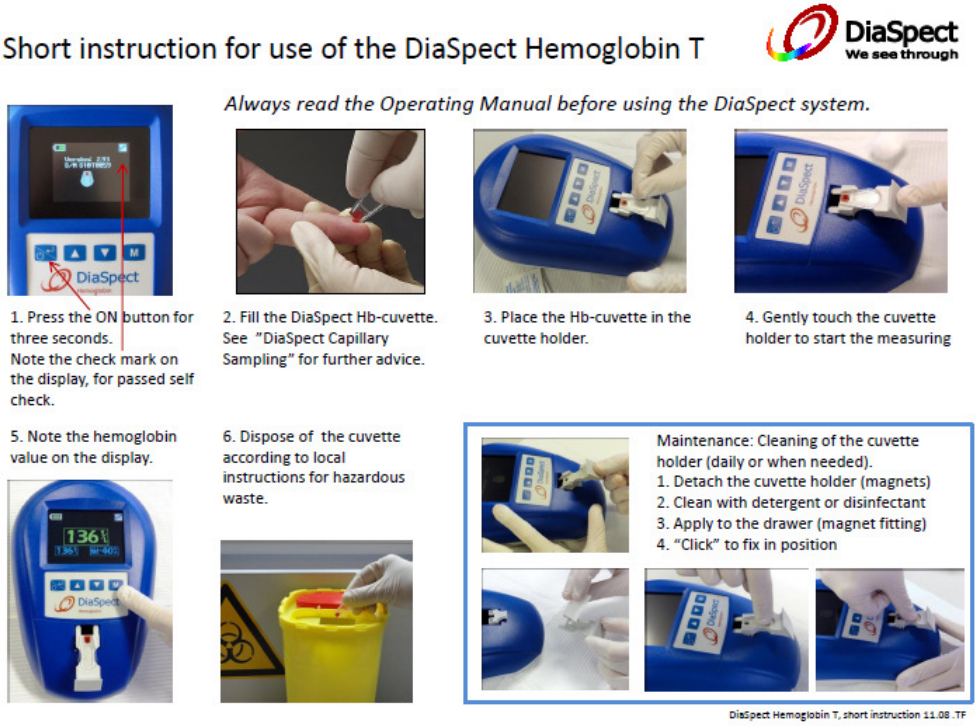
Is input of patient identification possible?	With DiaSpect data management (via USB cable)
Is input of operator identification possible?	With DiaSpect data management (via USB cable)
Can the instrument be connected to a bar-code reader?	With DiaSpect data management (via USB cable)
Can the instrument be connected to a printer?	With DiaSpect data management (via USB cable)
What can be printed?	Configurable
Can the instrument be connected to a PC?	Yes
Can the instrument communicate with LIS (Laboratory Information System)? If yes, is the communication bidirectional?	Data Management is implemented in a modular way and can be adapted to any available LIS A stand-alone solution is available that eliminates the need of a direct connection to a PC; connection to a LIS can be achieved by any standard communication interface, including LAN and WLAN
What is the storage capacity of the instrument and what is stored in the instrument?	The last measured result is stored and can be recalled by pressing the M-button
Is it possible to trace/search for measurement results?	With DiaSpect data management (via USB cable)

Table 3. Facts about the reagent/cuvettes

Name of the reagent/cuvettes:	DiaSpect Hemoglobin Cuvette (90C.0001)
Stability in unopened sealed vial:	2,5 years. Store at 0°C to +50°C. Temperatures of -30°C to +70°C are temporarily permitted during transport
Stability in opened vial:	2,5 years
Package contents:	100 cuvettes per bag; 5 x 100 cuvettes per box

Table 4. Quality control

Electronic self check:	Yes
Recommended control materials and volume:	DiaSpect Control HB. Three levels. 1,9 mL per vial
Stability in unopened sealed vial:	Until expiry date shown on the label
Stability in opened vial:	60 days
Package contents:	90B.0001_HB1: 3x1.9 mL DiaSpect Control HB-L (Low) 90B.0002_HB2: 3x1.9 mL DiaSpect Control HB-M (Medium) 90B.0003_HB3: 3x1.9 mL DiaSpect Control HB-H (High) 90B.0004_HB4: 1x1.9 mL DiaSpect Control HB-L 1x1.9 mL DiaSpect Control HB-M 1x1.9 mL DiaSpect Control HB-H Low: 77 – 83 g/L; 48 – 52 mmol/L Medium: 122 – 130 g/L; 76 – 81 mmol/L High: 154 – 166 g/L; 96 – 103 mmol/L



Short instruction in Danish, translated by SKUP **(used in the evaluation)**

1. ▪ Anvend lange- eller ringefinger
   ▪ Rengør indstikstedet
2. ▪ Indstik på **siden** af finger
3. ▪ Aftør de første **3** dråber
4. ▪ Kuvetten fyldes ved at holde på den brede ende og røre bloddråben med spidsen
5. ▪ Ydersiden af kuvetten aftørres
   ▪ Kontroller at kuvetten er fyldt korrekt
6. ▪ Placer straks kuvetten i DiaSpect
   ▪ Luk med et forsigtigt tryk
7. ▪ Hb koncentrationen aflæses efter et par sekunder
8. ▪ Korrekt bortskaffelse af kuvetten

Attachment 3 Supplier and Marketing information

Manufacturer and retailers in Scandinavia

Manufacturer:	DiaSpect Medical GmbH Von-Cancrin Str 1, 63877 Sailauf, Germany
Retailers in Scandinavia:	Denmark: Norway: Sweden: ANL-produkter AB, Box 26 Älvsjö, Sweden
In which countries is the system marketed:	Globally X Scandinavia X Europe X
Date for start of marketing the system in Scandinavia:	2011
Date for CE-marking:	2010-10-22
In which Scandinavian languages is the manual available:	Swedish

Attachment 4 Statistical expressions and calculations

This chapter with standardised text deals with the statistical expressions and calculations used by SKUP. The chapter is a short extract of the comprehensive SKUP-document "Statistics in SKUP reports", presented at www.skup.nu**,** under the option "The SKUP evaluation". The statistical calculations will change according to the type of evaluation. The descriptions in section 4.2 are valid for evaluations of quantitative methods with results on the ratio scale.

Statistical terms and expressions

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

Precision

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

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

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

Trueness

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

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

Accuracy

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

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

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

Statistical calculations

Statistical outliers

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

Calculation of imprecision

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

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

d = difference between two paired measurements
n = number of differences

(formula 1)

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

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

m = mean of paired measurements

(formula 2)

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

Calculation of bias

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

Assessment of accuracy

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

b. Burnett RW, "*Accurate Estimation of Standard Deviations for Quantitative Methods Used in Clinical Chemistry*". Clinical Chemistry 1975; **21** (13): 1935 – 1938
c. Saunders, E. Tietz textbook of clinical chemistry and molecular diagnostics. 2006. Chapter 14, Linnet, K., Boyd, J. "*Selection and analytical evaluation of methods – with statistical techniques*", ISBN 0-7216-0189-8
d. Fraser, C.G, Biological variation: *From principles to practice*. 2006. Chapter 1 "*The Nature of Biological Variation*". AACC Press. ISBN 1-890883-49-2

Attachment 5 Haemoglobin results from the comparison method

Raw data, Haemoglobin results, Sysmex in a hospital laboratory

	Sysmex			Sysmex	
	Instrument 1	Instrument 2		Instrument 1	Instrument 2
Sample no.	Haemoglobin mmol/L	Haemoglobin mmol/L	Sample no.	Haemoglobin mmol/L	Haemoglobin mmol/L
1	8,2	8,3	52	7,5	7,5
2	8,7	8,8	53	8,1	8,2
3	8,6	8,7	54	6,1	6,2
4	8,9	8,9	55	9,7	9,7
5	8,7	8,8	56	10,3	10,3
6	9,6	9,6	57	8,2	8,2
7	9,4	9,5	58	8,7	8,7
8	7,7	7,8	59	7,7	7,8
9	6,9	6,9	60	8,5	8,5
10	7,2	7,3	61	8,4	8,4
11	9,3	9,4	62	6	6
12	9,6	9,6	63	7	7
13	8,3	8,3	64	5,6	5,6
14	8	8,1	65	9,1	9,1
15	11,4	11,3	66	5,8	5,8
16	9,2	9,2	67	9,6	9,6
17	8,6	8,6	68	8,3	8,3
18	9	9	69	7,4	7,4
19	10,3	10,4	70	7,9	8
20	8,6	8,6	71	6,3	6,2
21	9,3	9,4	72	7,4	7,3
22	10,2	10,2	73	8,1	8,2
23	6,4	6,4	74	8,5	8,5
24	9,5	9,4	75	6,1	6,1
25	7,9	7,9	76	7,6	7,6
26	7,9	7,9	77	9,3	9,3
27	9,3	9,2	78	8,2	8,2
28	8,4	8,4	79	8,3	8,3
29	8,5	8,4	80	7,8	7,8
30	8,1	8,2	81	8,4	8,3
31	6,7	6,7	82	6,3	6,3
32	7,8	7,9	83	8,4	8,3
33	9	9,1	84	5	5
34	9,2	9,2	85	8,5	8,6
35	8,8	8,7	86	5,5	5,4
36	7,4	7,4	87	5,3	5,4
37	10,1	10,1	88	8,3	8,4
38	7,2	7,2	89	8,7	8,7
39	7,3	7,4	90	8,9	9
40	8,4	8,4	91	7,9	8
41	6,6	6,6	92	7,9	7,9
42	8,9	9,1	93	8,8	8,9
43	8,3	8,3	94	7,8	7,7
44	8,7	8,7	95	10,2	10,2
45	6,8	6,8	96	6,7	6,7
46	8,3	8,3	97	9,1	9
47	9,1	9,1	98	9,8	9,8
48	8,6	8,6	99	8,7	8,7
49	8,4	8,5	100	8,5	8,6
50	9,8	9,8	101	8	8
51	8,3	8,3	102	2,5	2,5

All the duplicate measurements from the comparison method originate from two Sysmex instruments.

Attachment 6 Internal quality control, DiaSpect Hemoglobin T, hospital laboratory

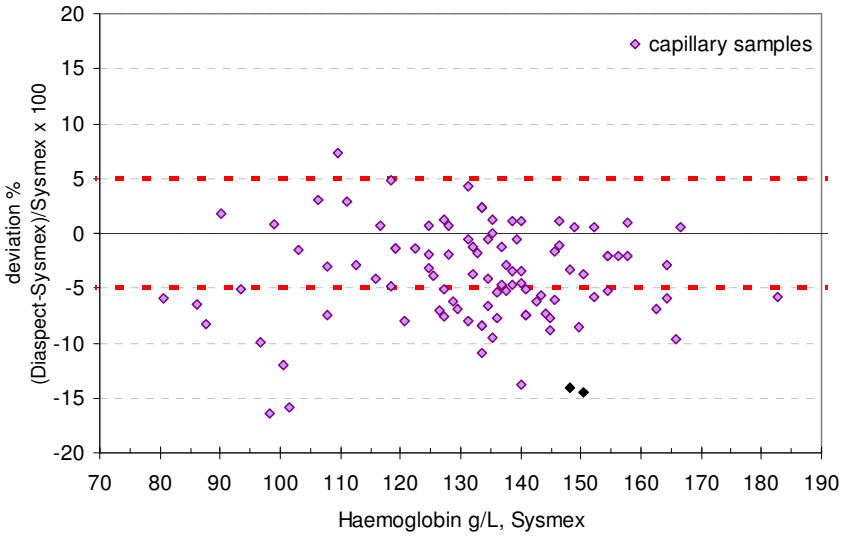
Raw data, DiaSpect Hemoglobin T hemoglobin in a hospital laboratory

date	low 1	low 2	medium 1	medium 2	high 1	high 2
11-05-2012	4,9	4,9	7,7	7,8	9,8	9,9
14-05-2012	4,9	4,9	7,8	7,7	9,8	9,8
16-05-2012	4,9	4,9	7,7	7,7	9,9	9,9
21-05-2012	4,9	4,9	7,7	7,7	9,9	9,9
23-05-2012	4,9	4,9	7,8	7,8	9,9	10
24-05-2012	4,9	4,9	7,7	7,7	9,8	9,8
30-05-2012	4,9	4,9	7,8	7,8	9,9	9,9
01-06-2012	4,9	4,9	7,7	7,7	9,9	9,9
04-06-2012	4,9	4,9	7,8	7,8	9,9	9,9
04-06-2012	4,9	4,9	7,8	7,8	9,9	9,9
13-06-2012	4,9	4,9	7,8	7,8	9,9	9,9
05-06-2012	4,9	4,9	7,7	7,7	9,9	9,9
14-06-2012	4,9	4,9	7,8	7,7	9,9	9,9
15-06-2012	4,9	4,9	7,8	7,8	9,9	9,9
18-06-2012	4,9	4,9	7,8	7,8	9,9	9,9
19-06-2012	5	5	7,8	7,8	9,9	9,9
20-06-2012	4,9	4,9	7,8	7,8	9,9	9,9
21-06-2012	4,9	4,9	7,7	7,8	9,9	9,9
22-06-2012	4,9	4,9	7,8	7,8		
25-06-2012					9,9	9,9
26-06-2012	5	4,9				
27-06-2012			7,8	7,8		
12-07-2012	5		7,7		9,8	
13-07-2012	4,9		7,7		9,7	
n	42		42		40	
Mean (mmol/L)	4,91		7,76		9,88	
cv%	0,6		0,6		0,5	

Attachment 7 DiaSpect Hemoglobin T Hemoglobin in a hospital laboratory

Raw data, DiaSpect Hemoglobin T hemoglobin in a hospital laboratory (only for client)

The accuracy of DiaSpect Hemoglobin T, with capillary and venous samples and three lots of test cuvettes is shown in figure Ia and Ib. The results in mmol/L are also shown in figur 2 and 3.



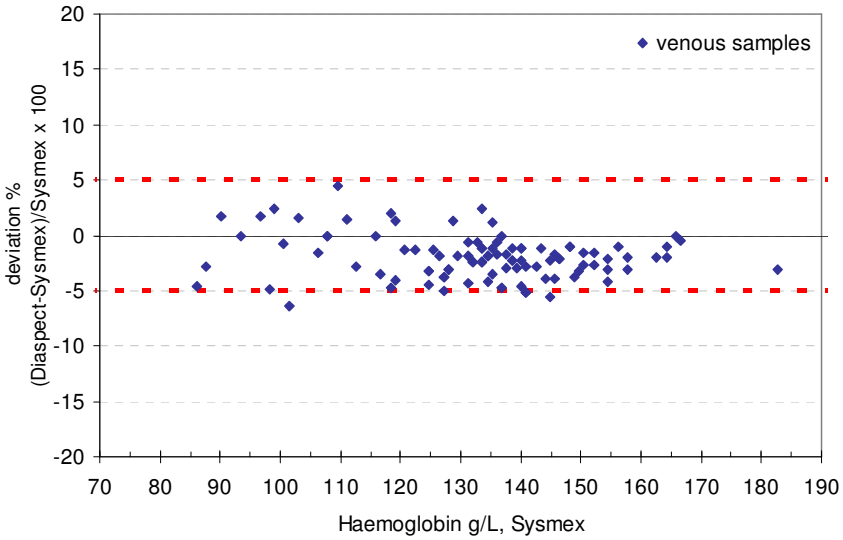


Figure Ia+Ib. Accuracy. DiaSpect Hemoglobin T (three lots of cuvettes) with capillary (figure Ia) and venous samples (figure Ib) in the hospital laboratory under standardised and optimal measuring conditions. The x-axis represents the mean result on the comparison method. The y-axis shows the difference between the first measurement on DiaSpect Hemoglobin T and the mean result of the comparison method. The stippled lines represent the limits for allowable deviation ±5,0%. ID 21 and 34, the statistical outliers from the calculation of repeatability in the high capilary results, are represented with closed black symbols, n = 101.

Attachment 8 Internal quality control DiaSpect Hemoglobin T in two primary health care centres

Raw data, DiaSpect Hemoglobin T in two primary health care centres

Primary health care centre 1

	low1	low2	medium1	medium2	high1	high2
	5	4,9	7,7	7,8	9,8	9,8
	4,9	4,9	7,8	7,8	9,8	9,8
	4,9	4,9	7,8	7,8	9,8	9,9
	4,9	4,9	7,7	7,7	9,8	9,8
	4,8	**4,8**	**7,5**	**7,5**	**9,5**	**9,5**
	4,8	**4,8**	**7,5**	**7,4**	**9,4**	**9,4**
	4,9	*4,9*	*7,8*	*7,7*	*9,9*	*9,9*
	4,9	*4,9*	*7,8*	*7,8*	*9,9*	*10*
	4,9	*4,9*	*7,8*	*7,8*	*9,9*	*10*
	4,9	*4,9*	*7,8*	*7,8*	*9,9*	*9,9*
	4,9	*4,9*	*7,8*	*7,8*	*9,9*	*9,9*
	4,9	*4,9*	*7,8*	*7,8*	*9,9*	*9,9*
	4,9	*4,9*	*7,8*	*7,8*	*9,9*	*9,8*
	4,9		*7,7*		*9,9*	
	4,9		*7,8*		*10*	
	4,9		*7,8*		*9,9*	
Mean (mmol/L)	4,90		7,78		9,88	

Instrument number 2 broke. The numbers in bold are excluded from the evaluation as a consequence of this. The results written in italic (blue) originates from instrument number 3

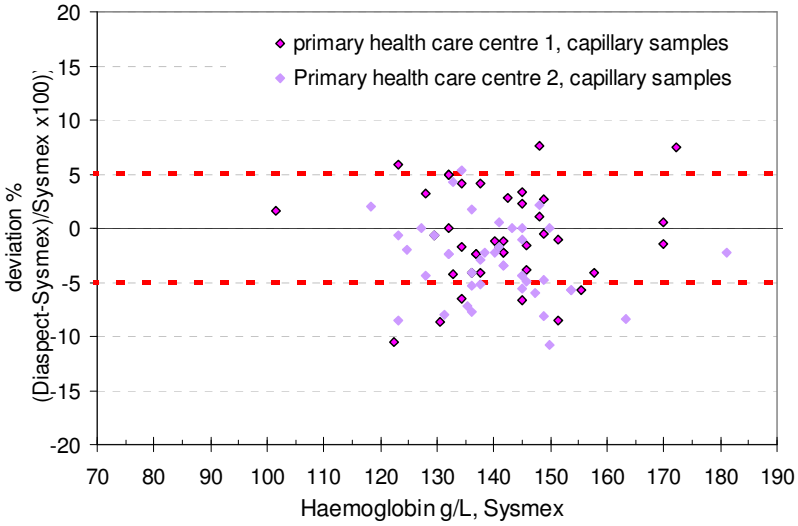
Primary health care centre 2

	low	medium	high
	4,9	7,7	9,9
	5	7,8	9,9
	5	7,8	9,9
	4,9	7,8	9,9
	4,9	7,7	9,9
	4,9	7,8	10,1
	5	7,7	9,9
	4,9	7,8	9,9
	5	7,9	9,9
	5	7,8	9,8
	4,9	7,8	9,8
	5	7,8	9,8
Mean (mmol/L)	4,95	7,78	9,89

Attachment 9 DiaSpect Hemoglobin T in two primary health care centres

DiaSpect Hemoglobin T results from two primary health care centres (rawdata only for client)

The accuracy of DiaSpect Hemoglobin T with capillary (fig IIa) and venous samples (fig IIb). The results in mmol/L are also shown in figur 4 and 5.



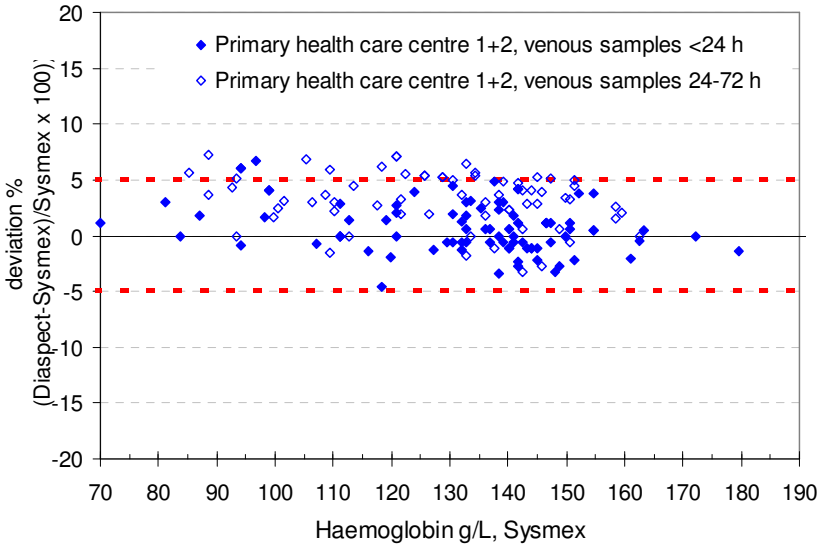


Figure II. Accuracy. DiaSpect Hemoglobin T with capillary (figure IIa) and venous (figure IIb) samples and three lots of cuvettes in two primary health care centres. The x-axis represents the mean result on the comparison method. The y-axis shows the difference between the first measurement on DiaSpect Hemoglobin T and the mean result of the comparison method. The dotted lines represent the quality goal limits of ±5,0%.

Attachment 10 List of latest 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.

SKUP evaluations from number 69 and further

Evaluation no.	**Component**	**Instrument/testkit**	**Producer**
SKUP/2013/96	Haemoglobin	DiaSpect Hemoglobin T	DiaSpect Medical GmbH
SKUP/2013/92	CRP	Eurolyser smart	Eurolyser Diagnostica GmbH Salzburg, Austria
SKUP/2012/95	Glucose[1]	Mendor Discreet	Mendor Oy
SKUP/2012/94	Glucose[1]	Contour XT	Bayer Healthcare
SKUP/2011/93*	Glucose	Accu-Chek Performa	Roche Diagnostics
SKUP/2012/91	HbA1c	Quo-Test A1c	Quoient Diagnostics Ltd
SKUP/2011/90	CRP	*i*-Chroma	BodiTech Med. Inc.
SKUP/2010/89*	Glucose	FreeStyle Lite	Abbott Laboratories
SKUP/2010/88*	HbA1c	*Confidential*	
SKUP/2011/86	Glucose[1]	OneTouch Verio	LifeScan, Johnson & Johnson
SKUP/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

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

[1] Including a user-evaluation among diabetes patients

Attachment 11 List of previous SKUP evaluations for Haemoglobin

SKUP evaluations for Haemoglobin

Evaluation no.	**Component**	**Instrument/test kit**	**Producer**
SKUP/2013/96	Haemoglobin	DiaSpect Hemoglobin T	DiaSpect Medical GmbH
SKUP/2006/47	Haematology	Chempaq XBC	Chempaq
SKUP/2004/29	Haemoglobin	Hemo_Control	EKF-diagnostic
SKUP/2002/23*	Haematology with CRP	ABX Micros CRP	ABX Diagnostics
SKUP/2001/17	Haemoglobin	Biotest Hb	Biotest Medizin-technik GmbH
SKUP/2000/6	Haematology	Sysmex KX-21	Sysmex Medical Electronics Co

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