Chempaq XBC
eXpress Blood Counter
manufactured by
Chempaq A/S

An instrument for B—Haemoglobin, B—Leukocytes and three-part differential count.

Report from an evaluation
organised by SKUP

Evaluated at the request of the Danish supplier
Chempaq A/S

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Evaluation of Chempaq XBC

CONTENT

Summary

In 2005 **t**he Danish manufacturer and supplier Chempaq AS ordered a SKUP evaluation of the Chempaq XBC (eXpress Blood Counter) device. Chempaq XBC is intended for measurements of Haemoglobin concentration, Leukocyte counts and three part differential (Lymphocytes, Monocytes and Granulocytes, concentrations and %) in the primary health care. In Chempaq XBC, each sample is analysed in a disposable cassette. Leukocytes, Lymphocytes, Monocytes and Granulocytes are counted and their size is determined in an impedance cell. Haemoglobin is measured photometrically at two wavelengths. The measuring interval for Leukocytes is 0-100 x 10^9/L and for Hgb. 0-13 mmol/L (1 mmol/L ~ 1,62 g/dL). The same type of cassette can be used for both capillary and venous blood samples.

In the first evaluation in primary care the cassette lots used had a bias due to a technical error that was eliminated in a second evaluation. The results of the evaluations are summarized in the table below.

Results *Outpatients, hospital and primary care evaluation 2. Suggested quality goals with grey background*

			Total Error, percent fulfilling the goal	
	Range	Type of sample	Hospital	Two primary care centres
Haemoglobin	(3 – 12 mmol/L)		± 5% deviation	
		Capillary Venous	83 % ≥ 95 %	68 and 78 % ≥ 95 %
Leukocytes	(3 – 25 x 10^9/L)		± 16% deviation	
		Capillary Venous	≥ 95 % ≥ 95 %	83 % and 95% ≥ 95 %
Granulocytes	(3 – 25 x 10^9/L)		± 23% deviation	
		Capillary Venous	95 % 89 %	95 and ≥ 95 % ≥ 95 %
Lymphocytes	(0,3 – 4 x 10^9/L)		± 21% deviation	
		Capillary Venous	95 % 92 %	85 % and ≥ 95% 92 %
Monocytes	(0,4 – 2,5 x10^9/L)		± 43% deviation	
		Capillary Venous	95 % ≥ 95 %	78 and 81 % 94 %

No agreed Scandinavian quality goals exist for Leukocytes and 3 or 5 part differentials. During the writing of the protocol for this evaluation, SKUP proposed the quality goals above. In the evaluation ≥ 95% of the results should fulfil the goals. For haemoglobin the Danish demands[1] for bias and imprecision are ≤ 2% and ≤ 3%, respectively.

In evaluation 2 Chempaq XBC fulfil the quality goals for haemoglobin and Leukocytes in venous samples. For capillary samples the goals were almost fulfilled in hospital under optimal conditions; however they are not fulfilled in primary care which may be attributed to capillary sampling. The deviation of the 3 part differential was almost within the quality goal for granulocytes and lymphocytes. The monocytes had a positive deviation for low concentrations, and Chempaq XBC seems to measure a slightly higher concentration of monocytes than Sysmex and Coulter.

The ratings of the 'Information in Manual', 'Time factors', 'Quality control' and 'Operation' were all 'satisfactory'. Both primary care centres found the instrument very easy to use; however they both pointed out that the application of the samples, especially the capillary ones, could be difficult. A special brand of glue made the results vanish from the printer paper after two weeks.
The error rate in the first evaluation was about 2%, while it had increased to 14% in the second evaluation due to an identified technical error.

1. Planning of the evaluation

1.1. a Background, SKUP evaluations

A SKUP evaluation is usually performed in a hospital laboratory and by two to four general practitioners. At least one of the general practitioners has a staff without a laboratory technologist. The Analytical quality and the user friendliness are evaluated both in the hospital laboratory and among the general practitioners. It has been a wish from the general practitioners in Denmark that analytical quality and user friendliness are weighted equally in the SKUP evaluations.

The aim of the hospital laboratory evaluation is to investigate the analytical performance and the user friendliness under standardised and optimal conditions. The performance of the system in the hospital laboratory is considered as the best quality the system can achieve. The evaluation in primary health care reveals the 'daily day user'-quality and pitfalls and is considered as the achievable quality under 'real' conditions.

1.1. b Background Chempaq evaluation

In 2004 SKUP in Denmark was asked to make a complete evaluation of Chempaq XBC during 2005. A protocol was written in Danish by Esther Jensen, M. Sc. Ole Blaabjerg and General Practitioner Per Grinsted.

SKUP and Chempaq have had the following meetings during 2005 and 2006:
1. Symbion Science Park, Copenhagen, 28th of February. Presentation of Chempaq XBC and SKUP
2. Odense 14th of March. Preliminary protocol.
3. Odense, 8th of April. Protocol, Discussion.
4. Odense, 25th of April. The protocol was approved by Chempaq A/S and the contract was signed. Education of laboratory technologists took place.
5. Odense, 10th of May. Preliminary data was presented. Testing in general practice could take place when Chempaq was able to provide two additional instruments.
6. Odense, 6th of January 2006. Report was discussed. It was decided to repeat the primary care evaluation in the same two centres.
7. May 2006. Final report.

The hospital laboratory evaluation was performed in the Department of Clinical Biochemistry, Odense University Hospital (OUH). M. Sc.,Ole Blaabjerg, from the department sets targets for Haemoglobin samples in Scandinavia according to the ICSH reference method. Two Danish general practitioners accepted to participate in the evaluation of the Chempaq XBC. None of them had a laboratory technologist employed.

Esther Jensen had the main responsibility for this evaluation. The evaluation in the hospital laboratory was done by the laboratory technologist Nina Brøgger. In the primary care centres, two nurses and doctors performed the tests. Cand. scient, Ole Blaabjerg, Department of Clinical Biochemistry, OUH was responsible for the testing in the reference laboratory.

The supplier Chempaq A/S signed a contract with SKUP 25th of April 2005. Chempaq A/S has supplied SKUP with the equipment necessary for the evaluation. After the protocol was approved, the personnel performing the evaluation were taught during 30 minutes how to perform the test. Esther Jensen has made the statistical calculations and written the report. Ole Blaabjerg and SKUP have approved the report. After the first round it was also sent to the supplier. They all got the opportunity to discuss and comment the report. The report will be published on Internet by SKUP

(www.skup.nu and www.SKUP.dk). After publication both SKUP and the manufacturer are allowed to use the results in further publications.

1.2. Addresses

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Primary care centres

General Practitioner Bak and Hansen, Odense, Denmark
General Practitioner Agertoft and Petersen, Odense, Denmark

2. Materials and methods

2.1. The Chempaq XBC instrument:

The Chempaq XBC is a new type of diagnostic test system for counting white blood cells and for quantifying haemoglobin. The Chempaq XBC technology offers a five-parameter test: Total number of White Blood Cells (Leukocytes, Lkc), three part differentials (Lymphocytes, Monocytes and Granulocytes) and Haemoglobin. All reagents are contained in the PAQ which means no external handling and storage of reagent bottles.

The test system comprises of two parts: a small disposable cassette, the PAQ (Particle Analyzer and Quantifier), and a Reader. The capillary blood sample (approx. 20 µL), obtained using a finger stick, is collected directly in the PAQ, which is then placed in the Reader. After three minutes, the result of the test analysis is displayed on the Reader. If the supplied printer is connected a printout is automatically made.


Chempaq XBC


Capillary samples


Venous samples


The reader and the PAQ
(**P**article **A**nalyzer and **Q**uantifier)

Technology

For Leukocytes the measurement principle is the Coulter principle or impedance cell counting and sizing. The principle is based on the change in impedance as cells suspended in a conductive liquid are aspirated through an aperture, formed in an electrically isolated membrane. A cell passing through the aperture will change the impedance and cause an electric pulse with amplitude proportional to the cell volume. The size of the change is dependent on cell volume; consequently the cells can be sub-grouped after size. The Chempaq XBC uses a cassette in which an aperture is placed. The aperture is produced in a polymer foil by micro laser technology. Chempaq XBC is designed for analysing fresh capillary blood direct from skin perforation or EDTA prepareted blood.

The measurement requires 20 µl of blood in order to fill the capillary tube in the PAQ, of which volume 3 µl is automatically introduced in the 'mixing' chamber by turning a valve when the PAQ is placed in the instrument. The 3 µl of blood is mixed with a reagent. The function of the reagent is 1) to hemolyse the erythrocytes, 2) oxidise the oxy-haemoglobin to a complex of met-haemoglobin and 3) transform the leukocytes, so the monocytes, lymphocytes and granulocytes become different in size. After mixing, the diluted test material passes the aperture where the cells are counted and classified after volume. Finally the haemoglobin content is determined spectrophotometrically in a special measuring cell. The end point of the reaction is measured bichromatically at the wavelengths 545 and 880 nm. The second wavelength is used to compensate for interference that might be caused by blood components like chylomicrons or leukocytes, or scratches on the surface of the cuvette. The haemoglobin concentration is calculated automatically and the result is shown on a liquid crystal display with the other parameters when the PAQ is removed from the reader. The measuring range is 0 – 13,0 mmol/L (0 – 20,9 g/dL).

The movement of the fluid is controlled by changing the pressure in the canals and chambers of the PAQ, while a pair of liquid detectors monitors the position of the liquid during the procedure. The results of measurements are shown on the display of the Reader after 3 minutes and can be printed by a special printer connected to the instrument.

Technical specifications

Chempaq XBC	
Size: (h x w x d) cm	13 x 18 x 30
Weight:	1.9 kg
No of test chambers	1
Incubation time	3 minutes
Level of noise	Max. 55 dBA
Current	120/240 VAC – 1,5 A
Working and storage conditions	
Allowed room temperature for the use of the instrument:	16°C – 35° C
Storage temperature	4°C – 30° C
Relative humidity while working	10 – 70 % non-condensing
Relative humidity (storage)	20 -85 % non-condensing
Air pressure	0.8 - 1.2 bar
Time from loading the casette to analysing	15 seconds
PAQ-cassette specifications	
Size: (h x w x d) cm	4,1 x 6,1 x 1,3
Weight	20 g
Storage (un-opened)	6 month (4°C – 30° C, 1 bar, 70% relative humidity)
Storage (opened)	24 hours (4°C – 30° C, 1 bar, 70% relative humidity)
Sample volume	20 µl, 3 µL blood is used

The Chempaq PAQ-system has reduced all liquid handling to a disposable cassette, which enables the device for point-of-care tests.

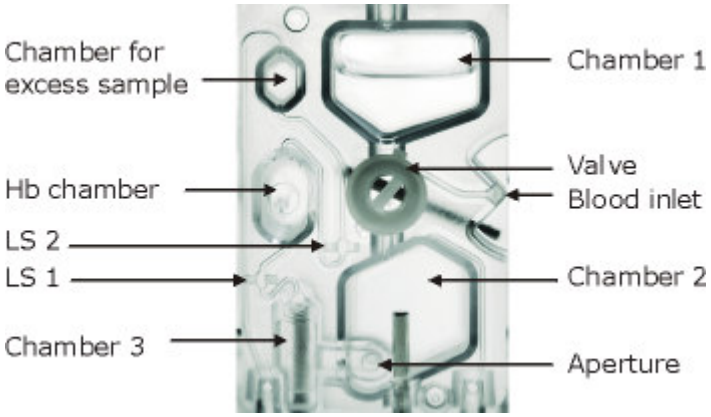
The Reader includes a docking station (cradle) for receiving the disposable PAQ.

All blood and reagents are confined within the PAQ, whereas the necessary electrical and fluid operations are controlled by the Reader through connectors in the cradle when the PAQ is inserted. The fluids in the PAQ are controlled by air pressure generated in the Reader. The fluid position is monitored by the Reader through optical detectors.

The Reader includes means for collecting the signals from the PAQ-cell counting sensor and an optical measurement system for determination of the haemoglobin content.

Blood Cell Counting in the PAQ

The PAQ is the disposable cassette, used for the blood sample. The same type of cassette is used for capillary or venous blood samples.



1. The capillary blood sample is collected directly in the blood inlet placed in the right side of the PAQ. For venous sample the blood is simply transferred to the inlet tray of the PAQ by means of a disposable pipette.
2. When the PAQ is placed in the Reader the valve is automatically turned to a vertical position.
3. The reagent from chamber 1 will pass through the tube into chamber 2 together with the blood sample (3 µL are used) where it is mixed by stirring.
4. The diluted blood sample is directed through the aperture and cell counting is started.
5. During filling of chamber 3 the PAQ is calibrated to perfect the counting.
6. When the liquid reaches the first level sensor (LS 1) the blood cell counting is started.
7. Cell count continues as Haemoglobin chamber is filled.
8. When the second level sensor (LS 2) is reached the blood cell counting is completed.
9. Measurement of Haemoglobin is carried out at two wavelengths (545 and 880 nm) through the Haemoglobin chamber.

Component	**Measuring range**	**Other units**
Haemoglobin (Hb)	0 – 13 mmol/L	0 – 21 g/dl (0 – 210 g/L)
White blood cells (Leukocytes)	0 – 99 x 10^9 /L	
Granulocytes (GRN)	0 – 99 x 10^9/L	%, (calculated)
Lymphocytes (LYM)	0 – 99 x 10^9/L	%, (calculated)
Monocytes (MON)	0 – 99 x 10^9/L	%, (calculated)

The printer

1 printer
1 cable (printer to Chempaq XBC instrument)
1 net adaptor
1 roll of paper* for the printer

* Printer paper: last for at least five years if stored at the right conditions (sensitive to heat and light over time)

PRINTER specification	
Size: (h x w x d) cm	7,0 x 10,6 x 14,8
Weight	330 g
Memory of data	Last result
Reported quantities	Haemoglobin, Leukocytes, 3 part differential (concentration and percent)
Power Supply	120/240 VAC – max 20W

Supplier: Chempaq

Supplier in	Denmark:	Chempaq A/S, Hirsemarken 1B, 3520 Farum
	Norway:	Orion Diagnostioca as, Solbråveien 43, Postboks 321, 1372 Asker
	Sweden:	Orion Diagnostica AB, Industrigatan 8, 619 33 Trosa

The information above is all according to Chempaq.

Possible sources of errors

• Haemolysis	no
• Triglycerides	no according to Chempaq, (1.3 – 17.95 mmol/L)
• Bilirubin, non-conjugated	no according to Chempaq, (17 – 257 µmol/L)
• Bilirubin, conjugated	no according to Chempaq, (3.4 – 86 µmol/L)
• Viscosity	part of testing
• Leukaemia cells	part of testing
• Calibration	not possible for the user
• Haematocrit	part of testing
• Carry over	no
• Air bobbles	yes
• Heparin	yes

2.2. Quality control

2.2.1. *Internal Quality*

'Built in' The Chempaq XBC system automatically performs a number of controls and calibrations before the beginning of each analysis. The result of the procedure is 'ready' or 'error' in the display.

From January 2006 Chempaq will provide liquid QC material at three levels. This have not been part of testing.
Human control: One person had capillary samples taken in duplicates during 20 days (blood sampling was not standardised according to time, fasting, physical exercise).
Genuine controls: 3 pools were made and analysed during 20 days

2.2.2. *External Quality*

The analytical quality of the Chempaq XBC was documented by means of the Coulter quality controls (high, low and medium) throughout the evaluation period. According to Chempaq the results for the five components should meet the criteria in the table 1 below.

Table 1. Example of the Coulter Control

Parameter	**Limits for Coulter Control** (depending on lot number)		
	Low*	**Normal**	**High**
LEUKOCYTES	1,3 – 2,5 x 10^9/L	4,2 – 6,1 x 10^9/L	11,0 – 13,7 x 10^9/L
HAEMOGLOBIN	3,6 – 4,4 x mmol/L	7,5 – 8,9 x mmol/L	10,1 – 12,1 x mmol/L
LYM	0,2 – 1,5 x 10^9/L	0,7 – 3,1 x 10^9/L	3,0 – 6,5 x 10^9/L
MON	0,1 – 0,5 x 10^9/L	0,4 – 1,1 x 10^9/L	1,0 – 2,3 x 10^9/L
GRN	0,3 – 1,7 x 10^9/L	1,3 – 3,7 x 10^9/L	4,2 – 7,5 x 10^9/L

* The low values are below the interval in which Chempaq expects to achieve the goals.

For Sysmex the normal daily controls (external and internal) were used.

2.2.3. *External Quality Control systems, (possibilities in Scandinavia)*

1) Normal, high and low control from other manufactures
2) Parallel analysing
3) 'Human control': A person with a known set point.
4) Schemes for External Quality Assurance

Denmark: For external Quality Control in primary care methods 1 to 3 is recommended[1] for Haemoglobin. There are no demands to Leukocutes and differentials and no Quality Control systems.

Norway For external Quality Control normal and abnormal level controls are used for Haemoglobin.

Sweden External Quality Assurance schemes and normal and abnormal level controls are used for haemoglobin.

Comparison method Leukocytes

In lack of an agreed reference measurement procedure for leukocyte count, we have used established hospital methods as comparison methods. The Coulter and Sysmex systems do not differ in national external quality programs.

2.3. Time schedule

The evaluation period:

Hospital laboratory	27th of April to 18th of June 2005
Primary Care, Denmark	June to October 2005

Writing of Report:

June 2005 to August 2005 (Hospital testing)
- Evaluation of report SKUP: September
- Report to SKUP and Chempaq: October

Report including primary care evaluation1: January 2006

Final report including primary care evaluation 2: May 2006

2.4. Materials

Four Chempaq XBC instruments were available for the evaluation: No 01R01N05, 01R06N03, 01R03N08, 01R01N06. The first instrument was used for hospital testing, and the last instrument was not used at all.
Evaluation 2: Chempaq XBC instrument: no 01R10N024
Cassettes: lot 108, 109, 110 112 and 112a were used, expiration date: October 2005.
Evaluation 2, Cassettes lot 131 was used.

Beckman Coulter liquid control 4C. Product number: 7547188. Control low, normal, high. Lot no 168691k, expiration date 13th July 2005.

Evaluation site	Number of test cassettes and controls used
Hospital laboratory (1 instrument and 1 as back-up)	
To get familiar with test (2 persons)	10 x 2 x 2 = 40
Intra-assay -/ Inter-assay variation	
Venous samples	140 x 2 = 280
Capillary blood	40 x 2 = 80
Control, low, high, normal	20 x 6 = 120
Two general practitioners (2 instruments)	
To get familiar with test (4 persons)	10 x 2 x 4 = 80
Intra-assay -/ Inter-assay variation	
Venous samples	40 x 2 x 2 = 160
Capillary samples	40 x 2 x 2 = 160
Controls	20 x 2 x 2 = 80

2.5. Reference measurement for Haemoglobin

All measurements are performed at the Department of clinical biochemistry, Odense University Hospital

Instrument: High performance spectrophotometer. UVIKON 942 (Kontron instruments). Equipped with a cell changer and a thermostat maintained at 22.5ºC ± 0.05ºC, wavelength 540.0 nm, bandwidth 1.0 nm. Baseline stability < 0.0002A/h. Readout: absorbance with 4 digits. Certified cuvettes with inner wall distance 1.000 ±0.001 cm.

External QC: Participation once a year in both the Finnish (LabQuality) and German (DGKC, Ringversuche) external quality control system for spectrophotometers including linearity, wavelength check and absorbance accuracy.

Method: The ICSH reference method (4th edition)[7] is followed except for these additions:

1. The specific density of the reagent and blood samples are measured (water bath ± 0.1 ºC)
2. Approximately 25 mL reagent and 100 µL blood (water bath ± 0.1 ºC) is pipetted into a volumetric flask. The exact volume is determined by difference weighing (semi micro analytical balance, readability 0.01 mg) in order to obtain a more accurate dilution factor (eg. 1:247.65 instead of 1: 250).
3. Cuvette tolerance 0.1% instead of 0.5%
4. Cuvette temperature 22.5ºC instead of 20-25ºC.

Traceability: A certified HiCN reference material (BCR CRM 522) was measured (fresh open) in the same four cuvettes during a 3 years period. We found a mean value of 100.10% of the recommended target value (range 99.79-100.27%. CV = 0.19%, n=6).

Control samples: A hemolysate prepared from washed red cells was kept at -80ºC and treated fully like patient samples. Measurement in triplicate during a five years period gave: mean 9.374 mmol/L. n= 25, CV-within 0.34% and CV-between = 0.35%.

Test samples: 9 different test samples were produced and analysed in triplicates (3 volume metric flasks). Result = mean ±2SEM

5.41 ± 0.018 mmol/L.
6.59 ± 0.011 mmol/L.
6.77 ± 0.014 mmol/L.
7.19 ± 0.008 mmol/L.
8.54 ± 0.001 mmol/L.
8.78 ± 0.019 mmol/L.
9.26 ± 0.053 mmol/L.
10.40 ± 0.040 mmol/L.
11.12 ± 0.020 mmol/L.

2.6. Hospital Laboratory

Comparison method, Department of clinical biochemistry, Odense University Hospital

Instrument: Sysmex I: SE-9000 (serie number A1837)
Sysmex II: SE-9000 (serie number A1836) The name of the System: HST 430

Coulter®LH 750 (755 workcell) (serie number AJ11184, AJ11186, AJ11190)

Method: The method for measurement of haemoglobin concentration is
Sysmex: Sodium Lauryl Sulfat (SLS).
Coulter: Hemochrom-S (HC-S)

Reagent: Several lot numbers have been used. Latest expiration date for them Oct 2005.

Sysmex			
	Haemoglobin:		Sulfolyser
		Cell counting:	Cellpack
			Stromatolyser - eos
			Stromatolyser - imi
			Stromatolyser – 3D
Coulter			Coulter®LH Servics Pak

Instrument for preparing manual diff: Miniprep, (now Hemaprep, Cellavision)

Colouring: Sysmex: The slides were colou red by SP-100
May-Grünwalds Eosin-methylenblue
Giemsa Azur-Eosin-methylenblue
Cellpack, lot no. 5016, expiration date 10th July 2005
Coulter Coulter ® TRUCOLOR May-Grünwald stain (lot 5200)
Coulter ® TRUCOLOR Giemsa stain

Instrument for counting manual diff: CellaVision DM 96 (S/N 31018).

Before and after the testing was started, the comparison instrument was tested against the haemoglobin reference method. Bias < 1%. Imprecision < 1%.

The samples were analysed randomly in the two Sysmex and the three Coulter instruments.

External quality assurance of the comparison method
Sysmex DEKS
Ringversuches “RET-IQAS”

Comparison method Leukocytes
During the testing period, the Sysmex used in the KKA, OUH had an estimated mean bias, as seen from two external assessment schemes of -3 to – 4%. The Sysmex values in this report are therefore adjusted for an estimated bias of -4%.

Coulter DEKS
Coulter IQAP

2.7. Materials and subjects

Hospital laboratory. Evaluation under standardised and optimal conditions

Blood samples were collected from 140 individuals during at least 20 days. In total, 142 venous samples and 40 capillary tests were analysed in duplicates. The first 40 individuals had both capillary and venous samples taken. They were all outpatients coming to the hospital for blood sampling. The rest had only venous samples taken. The distribution of the results was checked when about 70 random outpatients had had their samples taken. The last samples were chosen after the results of the comparison method to fulfil the predefined demands for the range of the results (table 2).

Table 2. Sample mix demand for Haemoglobin and Leukocytes:

	Group				
	A	B	C	D	E
Haemoglobin (mmol/L) range	<5,58	5,65 – 7,45	7,46 – 10,55		10,61 – 12,0
Haemoglobin (g/dL) range	<9	9,1 – 12,0	12,1 – 17,0		>17,1 – UL*
Leukocytes (x 10^9/L) range	<2	2,1 – 5,0	5,1 – 11,0	11,1 – 25	25,1 – UL
Proportion of samples demanded	10 %	20 %	40 %	20 %	10 %

* Upper Limit (UL)

Table 3. 40 special 'pathological' samples were chosen

	N, desired distribution	N, Minimum
Immature cells		8
'Blasts' 0-5%	1-4	
'Blasts' 5-10%	1-4	
'Blasts' 10-50 %	1-4	
'Blasts' > 50%	1-4	
Eosinofils		8
Eosinofils 5-10%	2-4	
Eosinofils 10-20%	2-4	
Eosinofils 20-40%	2-4	
Basofils		2
Basofils > 5%	2-4	
Lymphocytes		
Lymphocytes, Variant forms > 5%	4-6	4
Monocytes		
Monocytes > 10%	4-6	4
Leukaemia		
Myeloid, acute /chronic	≥ 6	6
Lymphatic, acute /chronic	≥ 6	6
Other cancer patients		
High viscosity	2-4	2

The purpose of including 'pathological' samples from hospitalised patients was to evaluate Chempaq XBC's capability of identifying abnormal samples. The objective was to measure if the eosinophilocytes were recognized as granulocytes. Lymphocytes, Variant forms are seen in patients

with Mononucleosis infectiosa, a relatively common disorder in general practise. It was investigated if the Chempaq recognize them with or without remarks? Many of the 'pathological' samples will not be released automatically by instruments in a hospital laboratory. Security systems detect them and they are examined in microscope by experienced laboratory technicians. It was also evaluated how these samples will be detected by Chempaq XBC.

2.7.1. *Preparation of tests used in the hospital laboratory*

Two laboratory technologists were taught by Chempaq (30 minutes) how to perform the test with Chempaq XBC. 138 patients that had a prescription for a differential cell count and 4 patients with abnormal haemoglobin levels were included.

40 random outpatients had capillary tests performed. From a finger stick, by a SOFTCLIX ®PRO 1,3 mm lancet, blood was filled directly into the PAQ cassette. Duplicate measurements were performed in two skin perforations, 1st and 2nd drop of blood were fluffed up.

In addition three EDTA samples were taken from one venous puncture. Type of tube: BD Vacutainer, K_2EDTA. Sample volume 4,0 ml. Catalogue number 368861.

The first venous sample was analysed as in usual routine. The second sample was immediately analysed in the Chempaq XBC instrument in duplicate (after the capillary samples in duplicate). The samples were analysed using five different lot numbers. All samples from one patient were analysed with the same lot number. Two slides for differential counting were then performed. The sample was saved in room temperature for the test period. Later, the third sample was re-analysed in the comparison method, Sysmex, as described above.

For the samples from the last 59 outpatients and from the 43 hospitalised patients only venous samples were measured, all the measurements were performed from the same tube in the following succession: Sysmex-Chempaq-Chempaq-Sysmex; two slides for cell counting were prepared by Miniprep, Coulter. The last outpatient samples and the 43 'pathological' samples were selected from a pool of routine samples based on the first value in the routine method.

All results were printed in paper. The slides were coloured by SP-100 (Sysmex).

A drop of fresh EDTA whole blood was applied into the application place in the PAQ cassette, according to the instructions from the supplier. It was checked if the cassette was filled correctly – that is blood should have passed the valve.

The measured result with one decimal is seen in the display when the PAQ is removed from the instrument. The results were also printed. Only result from the last sample can be seen in the display. The Chempaq XBC instrument displays an error code, e.g. "Error no 60" if the system detect errors. The error codes can be identified in the manual. All error codes displayed during the evaluation were noted.

2.7.2. *Preparation of tests used in the evaluation in Primary Care*

Inclusion: 40 patients who were ordered Leukocytes with cell counting or a measurement of C-Reactive Protein (CRP).

40 patients had capillary tests performed: blood from a finger stick was filled directly into the PAQ cassette. Duplicate measurements were performed (two skin perforations).

In addition two EDTA samples were drawn from one venous puncture. The first sample was analysed in duplicate in the Chempaq instrument during the same day. The second sample was sent to the comparison laboratory within 4 hours and analysed in duplicate the same day. Two slides for differential counting were performed at the hospital. The sample was then saved at room temperature for the test period.

An estimation of systematic deviation (bias) between the comparison laboratory and Chempaq XBC, CV_{within} and Total Error was part of this evaluation.

3. Demands/goals for analytical quality and User friendliness

3.1. Haemoglobin:

A Danish committee appointed by the National Ministry of Health has specified the demands to analytical quality[1] for haemoglobin for instruments used in primary health care. In the Danish goals, there are no demands to the total error, however they include quality demands to the comparison laboratory:

General practice	*a comparison hospital laboratory*
Bias $\leq 2\%$	Bias $\leq 1\%$,
$CV_A \leq 3\%$	$CV_A \leq 2\%$.

SKUP: Quality demands for allowable total error for haemoglobin

Total error: $< \pm 5$ % (95% of results)

3.2. Leukocytes and 3 part differential

No international (Golden) Standard for evaluation of instruments for the Leukocytes and 3 or 5 part differentials for primary health care or hospital laboratories exists.

Chempaq had some expectation to the performance of the Chempaq XBC, and it was decided to test if these expectations were achieved in relation to Sysmex as the comparison method.

Table 4. Quality goals

	Concentration	Bias (%)	Imprecision (%)	Total Error (%)
CHEMPAQ				
B—Leukocytes, count	3 – 25 x 10^9/L	$\leq \pm 5$	≤ 5	≤ 15
B—Lymphocytes count	0,3– 4 x 10^9/L	$\leq \pm 9$	≤ 13	≤ 35
B—Monocytes, count	0,3– 2,5 x 10^9/L	$\leq \pm 20$	≤ 28	≤ 66
B—Neutrophils, count	3 –25 x 10^9/L	$\leq \pm 7$	≤ 7	≤ 21
SKUP Desirable specification				
B—Leukocytes, count	3 –25 x 10^9/L	$\leq 6,6$	$\leq 5,5$	≤ 16
B—Lymphocytes count	0,3– 4 x 10^9/L	$\leq 12,0$	$\leq 5,2$	≤ 21
B—Monocytes, count	0,3– 2,5 x 10^9/L	$\leq 26,0$	$\leq 10,0$	≤ 43
B—Neutrophils, count	3 – 25 x 10^9/L	$\leq 9,1$	$\leq 8,1$	≤ 23

* Venous or Capillary. After beginning the testing SKUP decided for the goals in table. It means that the goals for imprecision and bias are lower for Leukocytes and granulocytes and higher for Lymphocytes and Monocytes.

To qualify for an overall good assessment in a SKUP evaluation, the measuring system must show both satisfactory analytical quality and satisfactory user-friendliness. Each area is subdivided and each subdivision has the following possible outcomes:

unsatisfactory
less satisfactory
satisfactory
very satisfactory

Each of the subdivision within Analytical quality and User friendliness has to achieve ‘satisfactory’.

User friendliness. Parameters evaluated
- manual /insert
- time factors
- quality control
- operation of the test

4. Statistical formulas

$$SD_{total} = \sqrt{\frac{\sum (x_j - \bar{x})^2}{N-1}} \qquad CV_{total} = \frac{SD_{total}}{\bar{x}_n} \cdot 100\%$$

$$CV_{within} = \sqrt{\frac{\sum \left(\frac{\Delta_i}{\bar{x}_i}\right)^2}{2n}}$$

N = total number of measurements, n = total number of samples. For duplicates N = 2n.
Δ_i is the difference between duplicates, and $\bar{x}_i$ is mean of duplicates for each sample.

Bias: Systematic deviation of Chempaq XBC in duplicates from the reference method/comparison method in duplicate

The allowable Total Error (TE) is calculated as TE = bias + z × imprecision, where z = 1,65. For each measurement the error is estimated as the difference between the first measurement on Chempaq XBC and the mean of the duplicate result with the comparison method.

95 % Confidence Interval for CV: calculated from inverse Chi^2 -distribution

Outliers[3]: $\bar{x} \pm k \times SD$

Table 5. From Burnett [3]

number	***k =***	***Number***	***k =***
10	2,8	100	3,47
20	3,02	120	3,58
30	3,14	150	3,58
40	3,22	200	3,66
60	3,33	300	3,76
80	3,41	400	3,83

4.1. Outliers

When analysing samples outliers can occur. SKUP uses the Burnetts model[3] to identify outliers. A possible reason for an outlier should always be detected. An initial result regarded as an outlier is excluded and not replaced by a re-analysed result.

Duplicate measurements and outliers

Upper limit, outliers: $\bar{x}_{diff} + k \times SD_{diff}$
Lower limit, outliers: $\bar{x}_{diff} - k \times SD_{diff}$

Outlier in duplicates is not used in imprecision.

The comparison method and outliers

Corresponding $\bar{x}$ in duplicates for the instrument and the comparison method is plotted in a scattergram, with the result from the comparison method on the X-axes and "Instrument – reference method/reference method × 100" on the Y-axes.

Limit for outliers: $\bar{x} \pm k \times SD$

5. Results and discussion

Chempaq XBC in hospital laboratory

142 samples were drawn from 140 different patients. From one patient three venous samples and two capillary samples were drawn. The total time span between the duplicate measurements (venous and/or capillary samples) for Chempaq was less than 30 minutes. The time span between the two Sysmex measurements was 66 minutes for the capillary samples, 205 minutes for the outpatients and 211 minutes for the hospitalised patients. All samples were analysed within 8 hours from sampling. This was according to the rules of the comparison laboratory. International guidelines recommend a maximum of four to six hours[18,19].

Chempaq XBC in Primary care, evaluation 1

40 patients in primary health care, for whom a CRP or a Leukocytes and a differential counting was ordered, two additonal EDTA blood samples were taken, one for the Chempaq XBC and one for the comparison method. A general practitioner or a nurse analysed the venous samples in duplicate (one glass) and two capillary samples (two skin penetrations) in Chempaq XBC. The two Primary care centres are called GP A and GP B.

The samples were taken between 8.00 and 11.00 in the morning. The blood samples for the comparison method were delivered at the hospital laboratory between 12.00 and 13.00. In the laboratory the samples were analysed before 14.00 with the comparison method in duplicate.

Reference method haemoglobin

Samples with assigned values from the reference method procedure were run before start of the evaluation, during the evaluation and when finishing the evaluation to make sure that the comparison method had no bias.

Bias in Hospital and Primary care

In the Primary care evaluation 1, there was a positive bias compared to the hospital evaluation for both haemoglobin and Leukocytes. The producer found that an unexpected evaporation of reagents had occurred in the cassettes used in the Primary care evaluation 1 after the release of the lots. If the valve is not lubricated sufficiently, evaporation can occur to a certain extent inside the sealed bag of the cassette. All cassette lot numbers lower than 130 were produced manually, some of the lots suffered partly from insufficient lubrication.

Chempaq XBC in Primary care, evaluation 2

Due to the problem with reagent evaporation discovered during evaluation 1, it was decided to repeat the evaluation, using a new lot number (131), which was manufactured automatically.

In the hospital evaluation and primary care evaluation 1, the Sysmex was the comparison method. At the time for the primary care evaluation 2, Coulter was the comparison method.

The goals for bias were not fulfilled in the primary care evaluation 1 for any component. The goals for imprecision, however, were fulfilled for almost all components with the venous samples in primary care evaluation 1. It was therefore decided to repeat the evaluation only for capillary samples in the primary care evaluation 2. The purpose was thus to investigate the bias and the 'optimal' imprecision after correction of the kit.

The results were from 40 random patients that were going to have a blood sample taken.

The primary care centres were the same as for evaluation 1. According to the protocol capillary samples should be measured in duplicates in Chempaq XBC. An additional tube with a venous sample was send to the comparison laboratory.

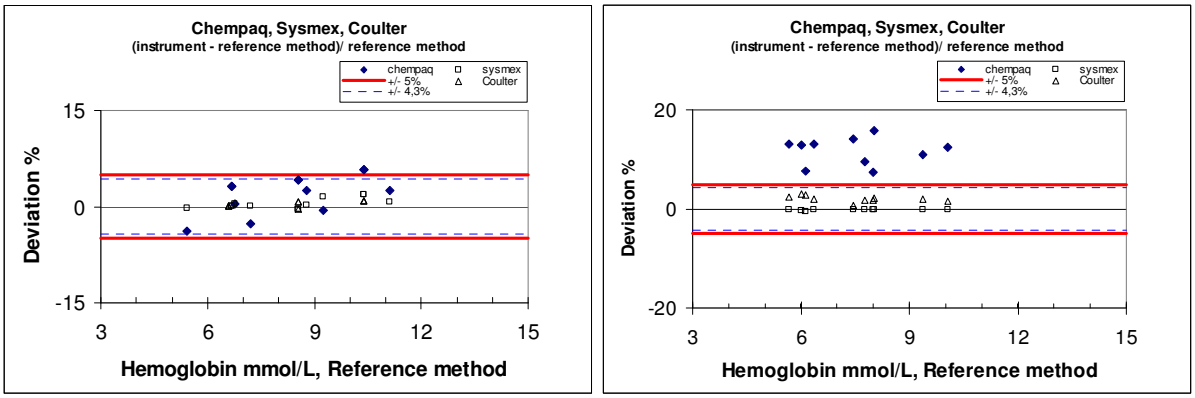
5.1. Reference method, Haemoglobin

During the evaluation in the hospital, samples with haemoglobin values assigned by the reference method procedure was also measured with the Chempaq, Sysmex, and Coulter instruments (figure 1). During the following evaluations in the primary care centres the procedure was repeated twice (figure 2).

To investigate the bias observed in the primary care evaluation 1, the same instrument used in primary health care, SN 01R03N08, was also used in the hospital by the same laboratory technicians that had performed the measurements in the hospital. 4 results were run in the reference method, Chempaq, Sysmex and Coulter. 40 days later the instrument used in the hospital testing, SN 01R01N05 was used in 6 samples against the reference method and Coulter. The results with the Chempac XBC and the reference method are seen in figure 2. Figure 3 demonstrates the results achieved with the Chempaq XBC instrument used in the hospital laboratory with lot used in the hospital testing. The results in figure 2 are made with lot 115 with two instruments from the primary care and the hospital laboratory evaluation. All the results are achieved by the two experienced laboratory technologists, which made the hospital testing.

It is seen that the hospital laboratory methods Sysmex and Coulter do not deviate from the reference method while Chempaq XBC has a positive bias during primary care testing (lot 115). The result > +5% in figure 1 was from lot 112a, which was used in both hospital and primary care.

Figure 1 and 2. Chempaq XBC comparison with Reference method



The diagrams show the deviation of the Chempaq, the Coulter®LH 750 (755 workcell) and the Sysmex hospital laboratory results. X-axis = mean of the reference method (triplicates) and Y-axis = ((test instrument result – mean value of reference method)/mean of reference method) x 100. SKUP Acceptance limits for Chempaq XBC results are ± 5 %. 95 % of the results should be within the acceptance limits.
Figure 1 demonstrates the results in the Chempaq XBC instrument used in the hospital laboratory with lot numbers used in the hospital testing before and during the test period. The results in figure 2 are obtained with lot 115 with two instruments (one from the primary care testing and the instrument used in the hospital) The testing was done during and after testing in primary care. All results are achieved by the same laboratory technologists. All samples deviating more than 5% originates from lot 112a or 115.

GP A only used lot 112a while GP B also used lot 115 for the last samples. The reason for the bias was therefore probably properties of lot 112a and lot 115. The bias for lot 112a and lot 115 was about the same. No cassettes from the laboratory testing (lot number 108-112a) were left over for further evaluations.

A Chempaq investigation of the remaining cassettes from lot 115 revealed an evaporation of reagents with an average of 7% as an explanation to the unexpected bias.

5.2. Types of patient samples, distribution of haemoglobin and leucocyte results

Samples from 99 outpatients and 43 hospitalised patients (venous special) were used. Of the hospitalised patients 19 had acute or cronic leukaemia, 9 had other types of cancer, 9 had severe infection during several month and 6 had other reasons for admission to hospital.

Table 6. Distribution of Haemoglobin results in Hospital laboratory (Sysmex duplicates)

	A	B	C	E
Haemoglobin (mmol/L) range	<5,58	5,65-7,45	7,46-10,5	10,6-12
Capillary samples, number (proportion)	1 (0,7 %)	4 (2,8 %)	35 (19,0 %)	0
Venous samples*	5 (3,5 %)	11 (7,7 %)	43 (30,3 %)	7 (4,9%)
'venous special'	7 (4,9 %)	26 (18,3 %)	9 (6,3 %)	1 0,7 %)

* The 40 patients that had capillary samples taken had also venous samples taken.

The range of concentrations for Haemoglobin in the samples in primary care evaluation 1 and 2 were similar. More than 90% belonged to range 7,46 – 10,5 mmol/L.

All measurements were registered. All results for Haemoglobin are used. No error signals were reported for Haemoglobin measurement in Chempaq.

5.3. Haemoglobin, Hospital and Primary Care 1

5.3.1. *Hospital laboratory, CV_{within}, Bias*

CV_{within}, bias in relation to Sysmex and total error were calculated for three levels of haemoglobin: the highest, the lowest and the middle concentration of Haemoglobin (33, 33 and 34%, respectively). The calculations were done for capillary samples, venous samples from out patients, and venous samples from selected hospitalised patients (table 7).

Table 7. Haemoglobin, Hospital Laboratory.
Analytical imprecision (CV_{within}) and Bias, venous and capillary samples.

Sysmex					Chempaq						
Sample		N	Mean (range) mmol/L	CV_{within} %	Sample	N	Bias %	95 % CI %	N	CV_{within} %	95% CI %
	Venous	*48*	*8,57 (4,40 – 10,00)*	*0,8(0,7 – 1,0)*	Capillary	40	-1,7	-2,4 – -0,9	40	2,33	1,9 – 3,0
Low	*Venous*	*48*	*6,10 (4,30 – 7,25)*	*0,9(0,7 – 1,1)*	Venous	44*	2,4	1,8 – 3,1	47	1,53	1,4 – 1,7
Mean	*Venous*	*47*	*7,93 (7,25 – 8,70)*	*1,0(0,7 – 1,2)*	Venous	47	1,8	1,3 – 2,3	47	1,17	1,1 – 1,3
High	*Venous*	*48*	*9,55 (8,75 – 11,10)*	*0,7(0,5 – 0,8)*	Venous	48	1,8	1,2 – 2,3	48	1,42	1,3 – 1,6
All	*Venous*	*141*	*7,86 (4,30 – 11,10)*	*0,8(0,8 – 1,0)*	Venous	139*	2,0	1,8 – 2,4	141	1,39	1,2 – 1,6

*Two outliers according to Burnett, (no. 1139 and 1142). Bias is calculated from the Chempaq duplicates

5.3.2. *Primary care. Evaluation 1.*

Imprecision (CV_{within}), Bias (table 8) and the Total Error (table 10) were calculated for samples from the two primary health care centres for capillary samples and venous samples taken from out patients.

In GP B seven venous samples were not performed in duplicate and one sample could not be measured on the comparison method due to coagulation. In 4 samples 'Error 60' occurred. One capillary sample was not reported because the printer was off.

For CV_{within} there was a difference for venous and capillary samples. The repeatability for the first 20 results was compared to the repeatability for the last 20 measurements. The results demonstrated a difference indicating that it take more than 10 samples to learn how to use Chempaq (table 9). It was tested, that the results were not due to concentration of the samples (data not shown).

Table 8. Haemoglobin, Primary Care, Evaluation 1.
Analytical imprecision (CV_{within}) and Bias, all venous and all capillary samples.

	Sysmex			Chempaq						
GP	N	Mean (range)	CV_{within} (95CI%)	Sample	N	Bias	95 % CI	N	CV_{within}	95% CI
		mmol/L	% (%)			%	%		%	%
A	40	8,52 (5,9-10,0)	*0,42(0,3—0,5)*	Capillary	40	4,4	3,2—5,6	40	4,6	3,8—5,9
				Venous	40	6,0	5,4—6,5	40	1,6	1,3—2,1
B	39	8,24 (7,1-9,6)	*0,45(0,4—0,6)*	Capillary	34	5,1	2,8—7,4	35	7,4	5,9—9,7
				Venous	33	6,3	5,6—6,9	33	2,0	1,6—2,6

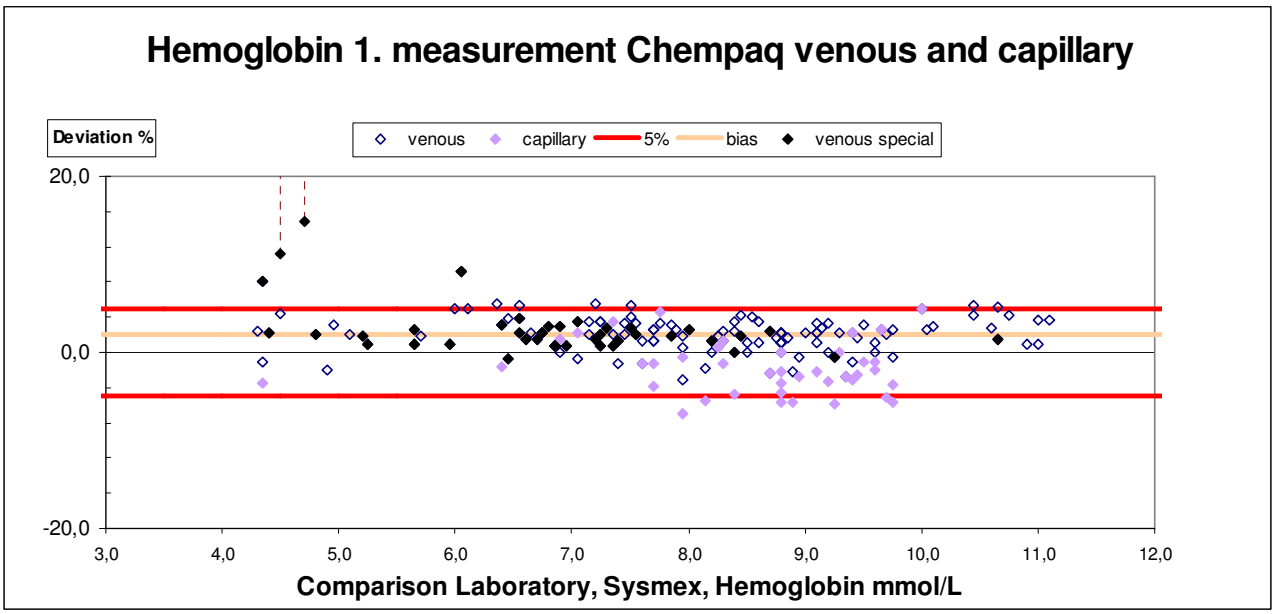
Table 9. Haemoglobin, Primary Care, Evaluation 1. Results from the first 20 samples versus last 20 samples. Analytical imprecision (CV_{within}) and Bias for venous and capillary samples.

GP	Sample	Sample no	N	Bias	95 % CI	N	CV_{within}	95% CI
		mmol/L		%	%		%	%
A	Capillary	1-20	20	4,1	2,5—5,7	20	4,5	3,5—6,5
		21-40	20	4,6	2,7—6,4	20	4,7	3,7—6,9
	Venous	1-20	20	5,6	4,7—6,5	**20**	**1,8**	**1,4—2,7**
		21-40	20	6,3	5,6—7,0	**20**	**1,3**	**1,0—1,9**
B	Capillary	1-20	16	2,3	-2,3—6,8	17	10,0	7,3—16,3
		21-40	18	7,6	6,1—9,1	18	3,2	2,4—4,6
	Venous	1-20	13	5,4	4,3—6,5	13	2,2	1,6—3,5
		21-40	20	6,8	6,1—7,6	**20**	**1,9**	**1,4—2,7**

Both primary care centres did mention that they found the application of the samples difficult. Sampling problems and ‘different degrees of lubrications of the valves’ could explain the imprecision found for capillary samples. In GP B it was seen that familiarisation might reduce imprecision to 3-4% in capillary samples.

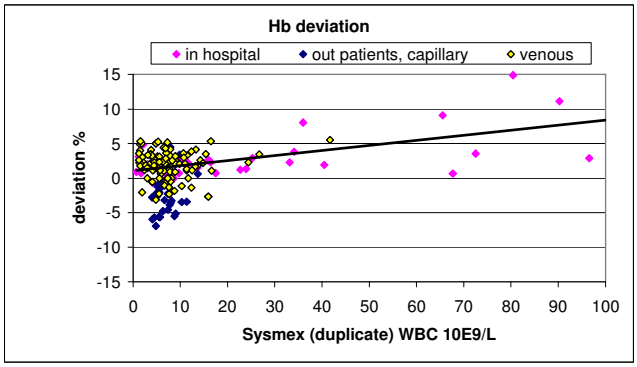
5.3.3. *Hospital laboratory, Total Error*

Figure 3. Total Error. Hospital Laboratory.



The diagram shows the deviations of the Chempaq XBC results with capillary and venous samples. X-axis = mean of comparison method, duplicate results, and Y-axis = ((first Chempaq XBC result– mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. Acceptance limits for Chempaq XBC is ± 5 %. 95 % of the results should be within the acceptance limits. Bias for the venous samples is demonstrated with beige line. ---Two outliers according to Burnett. All four 'venous special' samples above the 5 % limit originated from patients with leukaemia and the measurements are performed with lot no. 112a.

Figure 4 and 5. Haemoglobin deviation as a function of Leukocyte concentration



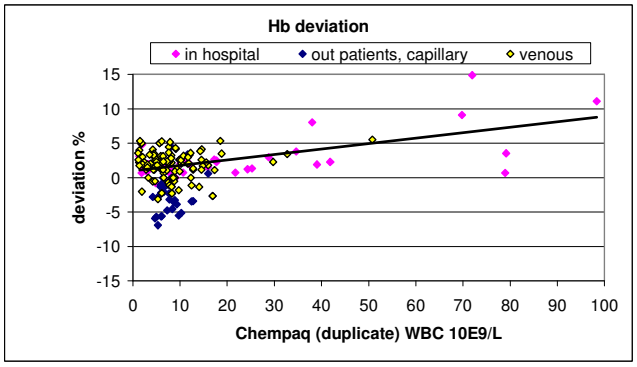


Figure 4 shows the deviation of haemoglobin as a function of Sysmex Leukocyte duplicate counts and Figure 5 as a function of Chempaq Leukocytes duplicate count. The figures illustrate that the measured concentrations of haemoglobin increases slightly with large Leukocytes counts. However, the effect could also be attributed to the properties of the cassettes from lot 112.

Table 10. Haemoglobin, Chempaq XBC. Hospital laboratory. Total Error

Haemoglobin	Interval mmol/L	N	Deviation < ±5% %	Deviation 95% within limits*
Capillary samples	8,57 – 10,0	40	82,5	< ±5,7%
Venous samples	4,30 – 7,25	44**	93,3	< ±5,6%
Venous samples	7,25 – 8,70	47	97,9	—
Venous samples	8,75 – 11,10	48	95,8	—
All		141**	95,0	—

* Percentage limits for 95% of results. **two outliers according to Burnett, (no. 1139 and 1142). Total error is calculated from 1st. value in Chempaq

Haemoglobin. Outpatients. Venous and capillary samples

Figure 6. Total Error. Hospital laboratory

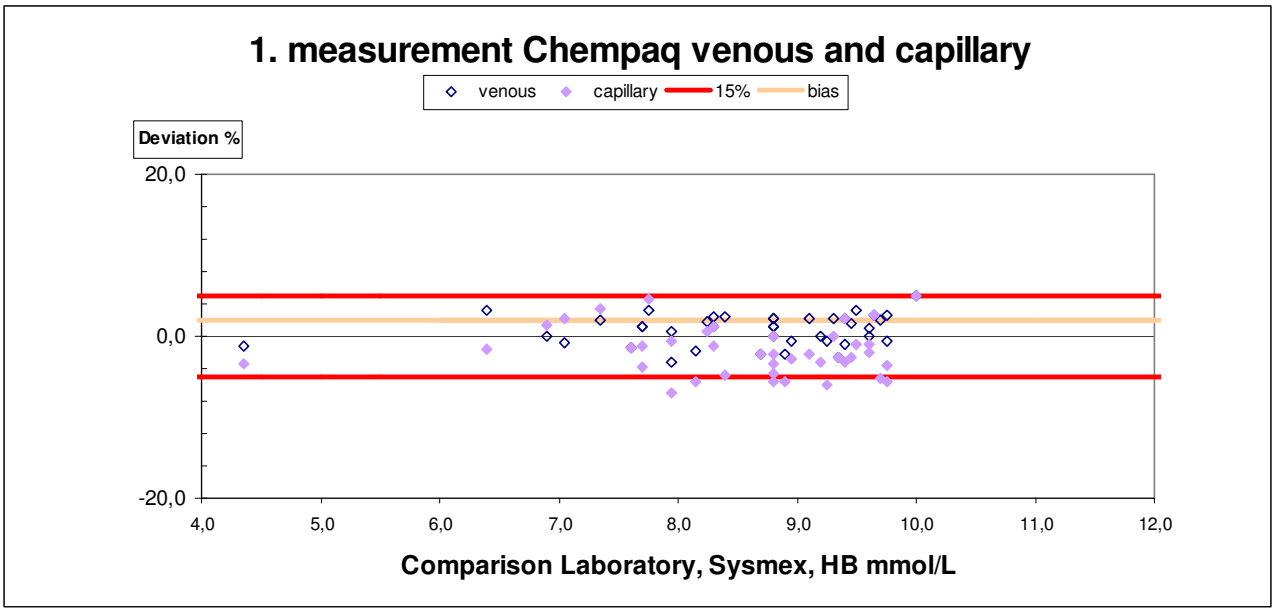
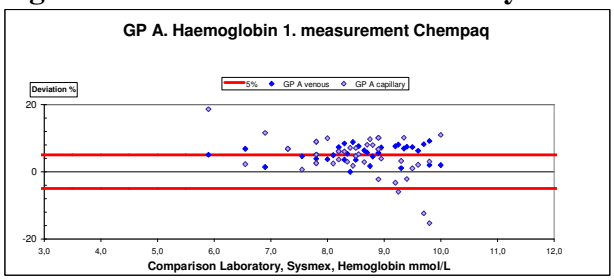
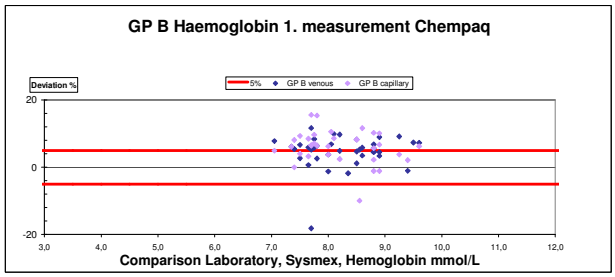


Figure 7 and 8. Total Error. Primary Care Evaluation 1.





The figures shows the deviations between the Chempaq XBC results and the comparison method for capillary and venous samples at two different General Practitioners laboratory. X-axis = mean of comparison method, duplicate results, and Y-axis = ((first Chempaq XBC result – mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. Acceptance limits in red for deviations ± 5 %. 95 % of the results should be within the acceptance limits.

Table 11. Haemoglobin, Chempaq XBC. Primary Care. Evaluation 1

	Haemoglobin	Interval Mmol/L	N	Deviation < ±5% %	Deviation < ± 6% %	Deviation 95% within limits*
GP A	Capillary samples	6,7 – 11,1	40	45	52,5	± 13%
	Venous samples	6,2 – 10,7	40	35	50,0	± 9%
GP B	Capillary samples	6,7 – 10,3	40	35	37,5	± 15,5%
	Venous samples	6,3 – 10,3	40	40	60	± 10%

*percentage limits for 95% of results.

Validation of the Hospital evaluation

Bias, or systematic deviation from the comparison method: The haemoglobin concentration as measured with Chempaq in capillary samples showed a negative deviation of -1,7 % compared to that measured with Sysmex in venous samples. The haemoglobin concentration as measured with Chempaq in venous samples showed a positive deviation of 2,0 % compared to that measured with Sysmex in venous samples (figure 3). Such discrepancy has not been seen in the SKUP evaluations no. 6 or no. 29, but it was seen in SKUP/2001/17. In no. 17 there was a discrepancy between high and low values, which is not seen here.

In the literature capillary samples have been described to have higher haemoglobin concentration than the corresponding venous samples[21-26]. We have no explanation for the slightly, but significant lower concentration in the capillary samples found in the hospital evaluation of this study. The difference was not reproduced in primary care (figure 12).

In total 9 venous patient samples with Chempaq deviated > +5% from the Sysmex resuls. They were all analysed with lot 112a and they were all selected due to abnormal Haemoglobin or leukocytes values. Six of them were from patients with leukaemia (including the 2 outliers), of which two had leukopenia (Leukocytes < 2,0x 10^9/L) due to treatment.

Compared to Sysmex, four hospitalised patients with acute leukaemia deviated more than +8%. The rest deviated less than +5,6%. It is known from previous investigations that a high number concentration of leukocytes can interact with the spectrophotometric measurement of haemoglobin[14]. However, the Chempaq XBC device measure at two wavelengths, in order to minimize interference from leukocytes.

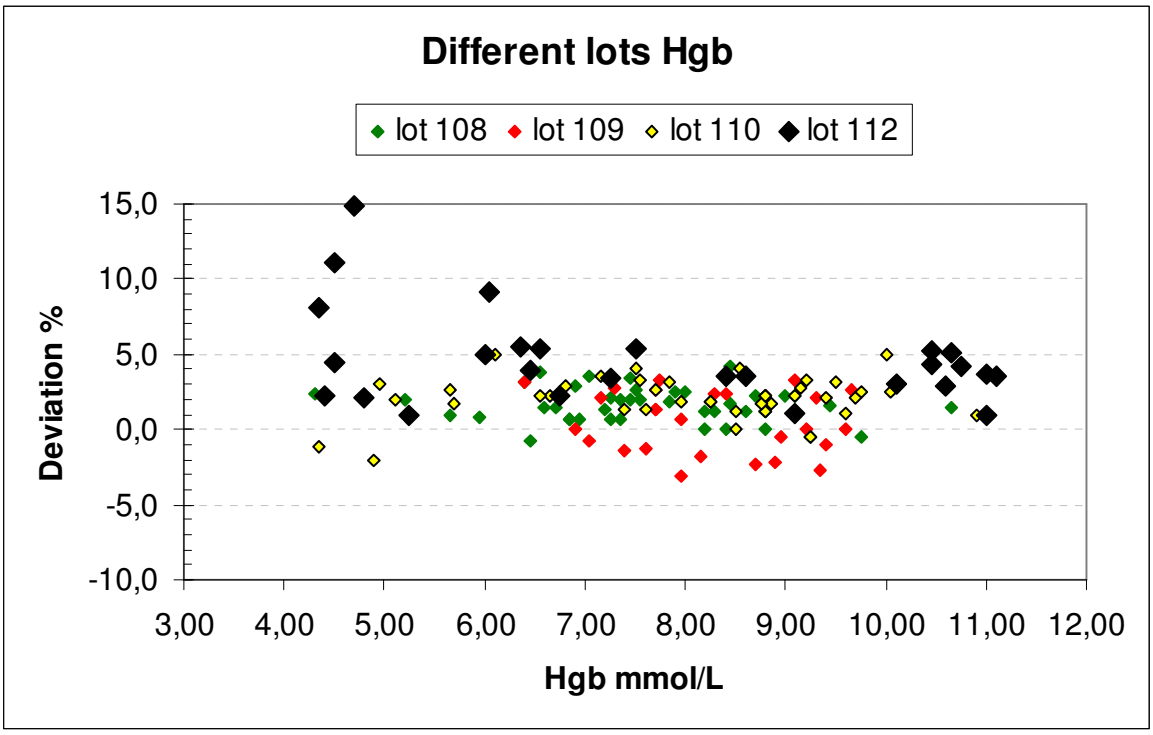
Of the 16 individuals with Leukocytes > 20 x 10^9, five deviated > +5% (Four of the patients suffered from acute leukaemia and one from chronic lymphatic leukemia).

Validation Primary care Evaluation 1:

Estimated bias for the capillary Haemoglobin was 4.4-5.1% and for the venous blood samples about 6%. This was higher than the expectation of max 3% of both SKUP and Chempaq. This was also higher than in 40 outpatients in the hospital laboratory. In the hospital laboratory there was a bias below 3% and there was a difference between the venous samples and the capillary samples from the same patient. This was not seen for the primary health care centres.

Lot 112a was also used in the hospital testing; only results from lot 112a deviated more than 5%. It was proved (figure 1, 2 and 9) that the deviation was due to the lot number. We did not re-investigate patients with leukaemia.

Figure 9. Total Error. Chempaq, venous samples in hospital laboratory.



Imprecision

The quality goals were achieved for the measurements of venous blood samples with a CV% of 1.6 to 2.0%. The imprecision for the capillary Haemoglobin was from 4.6 to 7.4 % in the primary care centres. This is higher than the expectation of 2% of both SKUP and Chempaq.

In GP A, the imprecision of the measurements of the venous samples fell from 1.8 to 1.3 from the fist 20 samples to the last 20 samples indicating, that the familiarisation should be more than 10 samples. However, nothing happened to the imprecision in the capillary samples in GP A (4.5 and 4.8%).

In GP B the performance of the capillary samples improved significantly in the last 20 samples (CV improved from 10.0% to 3.2%).

Total Error

In Primary care only the goals/specifications for imprecision in venous samples were achieved in the first evaluation. Bias and the demands to the total error were not fulfilled in Primary health care centres.

By testing different instruments over time and comparing results with reference method it was demonstrated that the reason for not achieving the goals was confined to the lot numbers 112a and 115. The reagent volume in the cassettes had diminished by evaporation with in average 7%, as explained further in enclosure A.

5.4. Haemoglobin, Primary care 2

Primary care. Evaluation 2, Imprecision (CV_{within}), Bias
Shortly after start of evaluation 2, GP A reported high frequency of error signals from the Chempaq device. The same instrument was used as in the previous evaluation 1. Even after replacement of the instrument the frequency of error signals was still about 33 %. Both instruments were referred to Chempaq for further investigation, and replaced by a third instrument (01R10N024).

Chempaq attributed the increased error frequency to a possible defect the lot of PAQs used. See the enclosed technical explanation from Chempaq.

Despite the elevated frequency of error signals, Chempaq suggested the study to continue. The appearance of Error Codes resulted in a high number re-analysis, but was not expected to otherwise influence the performance of the instrument. All other users of the instrument were at the same time informed of the risk of errors and offered compensation for it. (See enclosure B).

Table 12. Haemoglobin, Primary Care evaluation 2.
Analytical imprecision (CV_{within}) and Bias, all venous and all capillary samples.

	Sysmex			Chempaq						
GP	N	Mean (range)	CV_{within} (95CI%)	Sample	N	Bias	95 % CI	N	CV_{within}	95% CI
		mmol/L	% (%)			%	%		%	%
A	*40*	*8,9(6,7 – 10,6)*	*0,47(0,4 – 0,6)*	Capillary	39*	2,6	1,9 – 3,4	39	**2,9**	2,4 – 4,0
				Venous	32	2,1	1,4 – 2,8	32	**1,3**	1,1 – 1,7
B	*42*	*8,7(6,8 – 10,3)*	*0,56(0,5 – 0,7)*	Capillary	40*#	**2,0**	1,0 – 3,0	41*	**3,0**	2,5 – 3,8

*1 outlier, #single result. GP A had a high percentage of errors in the beginning and was asked to measure venous samples.

Total Error
Figure 12.

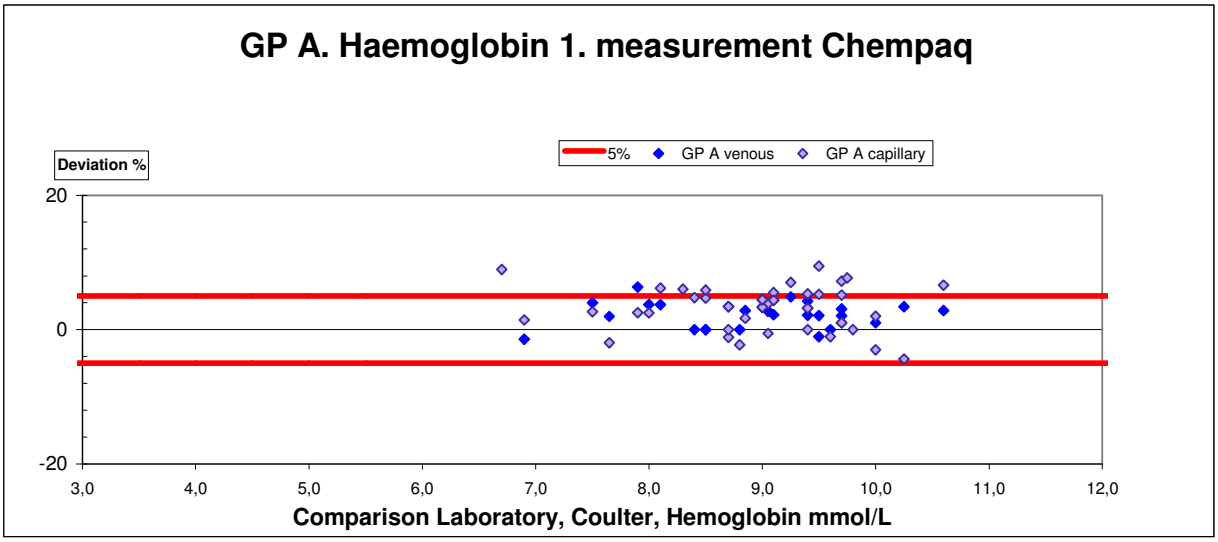
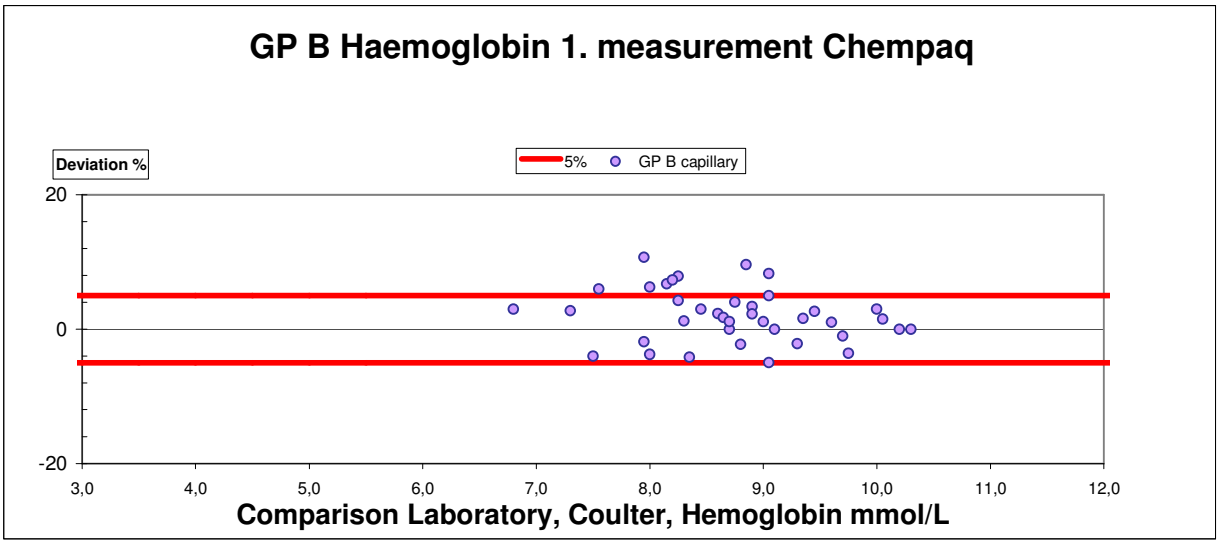


Figure 13.



The figure 13 shows the deviations of the Chempaq XBC results with capillary (and venous figure 12) samples in two General Practitioners laboratory. X-axis = mean of comparison method, duplicate results, and Y-axis = ((first Chempaq XBC result – mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. Acceptance limits for SKUP is ± 5 %. 95 % of the results should be within the acceptance limits.

Table 13. Haemoglobin, Chempaq XBC. Primary Care. Evaluation 2.

	Haemoglobin	Interval Mmol/L	N	Deviation < ±5% %	Deviation 95% within*
GP A	Capillary samples	7,0—11,3	39**	67,5	± 8%
	Venous samples	6,8—10,9	32	97,5	± 4,5%
GP B	Capillary samples	5,8—10,3	40	77,5	± 10%

* Percentage limits for 95% of results. **One outlier 2,2mmol/L.

More than 95% of the results from venous samples were inside the limit of ±5% from the comparison method in GP A. Only 67,5 and 77,5% of the capillary samples were within the acceptance limits in GP A and GP B respectively. The SKUP demands of Total Error less than 5% for more than 95% of the results was not fulfilled capillary samples. As seen in the table 13, 95% of the results from primary care were within ±8-10%.

The Danish demands of Bias ≤ 2% and CV ≤ 3% and was fulfilled for GP B, while the bias in GP A exceeded 2 % (2,1% for the venous samples and 2,6% for the capillary samples).

Conclusion Haemoglobin

The samples from the hospital laboratory where measured by an experienced laboratory technologist. The results did fulfil the quality goals for both venous and capillary samples regarding allowable bias, imprecision and total error.

For primary care Chempaq XBC did fulfil the SKUP demands for venous samples, but not for capillary samples. The latter was due to a positive bias of about 2-2,6% combined with an imprecision of 3% for the capillary samples. The results are similar with previous findings in SKUP evaluations for haemoglobin concentration in capillary samples (SKUP/2001/17 and SKUP/2004/29). The reason is most likely pre-analytical errors due to the capillary sampling. Both primary care centres did mention that they found application of the capillary samples difficult.

5.5. Leukocytes, Hospital and Primary Care 1.

Chempaq XBC in hospital laboratory

All measurement results are registered and used for this analysis. 34 samples from the comparison method Sysmex had flags on at least one of the duplicate measurements for Leukocytes or differential count. 21 of the samples was marked with * in at least one of the duplicate measurement with Chempaq. The Chempaq marking was always in all of 7 results (Lkc, LY, MO, GRN and LY%, MO% and GRN%)

Table 14. Distribution of Leukocytes results (Sysmex duplicates)

	A	B	C	D	E
Lkc, * (x 10^9/L) range	< 2	2,1-5,0	5,1-11,0	11,1-25	25,1-200
Capillary samples, number (proportion)	0 (0 %)	7 (4,9 %)	29 (20,4 %)	3 (2,1 %)	0 (0 %)
Venous samples*	11 (7,7 %)	17 (12,0 %)	16 (11,3 %)	14 (9,9 %	2 (1,4 %)
'venous special'	6 (4,2 %)	7 (4,9 %)	9 (6,3 %)	9 (6,3 %)	12 (8,5 %)

* Including two samples that were < 1 x 10^9/L and one sample > 100x10^9/L. The 40 patients that had capillary samples taken had also venous samples taken.

Over 80% of the samples collected in primary care evaluation 1 contained Leukocytes counts, as estimated by the Sysmex, in the interval between 5,1 and 11,0 x 10^9/L. All measurements were registered. All results for Leukocytes were used.

Analytical quality Leukocytes

5.5.1. *Hospital Laboratory, CV_{within}, Bias*

Bias and CV_{within} were calculated for capillary and venous samples from out patients, and from venous samples from hospitalised patients (table 15). For the venous samples CV_{within} and Bias were calculated for three subgroups: the highest values (33%), the lowest (33%) and the middle level of Leukocytes (34%).

Table 15. Leukocytes, Hospital Laboratory, Chempaq XBC

Analytical imprecision (CV_{within}), Bias and total Error. Venous and capillary samples.

	Sysmex			Chempaq						
	N	CV_{within} %	Mean (range) Lkc x 10^9/L	Sample	N	Bias # %	95 % CI %	N	CV_{within} %	95% CI %
Outpatients Hospital										
	40	4,3 (3,6—5,4)	7,04 (3,0—15,9)	Capillary	40	**1,2**	-1,2—3,6	40	**5,3**	4,3—6,7
				Venous	40	7,4	6,0—9,0	40	**2,0**	1,6—2,5
All patients										
Low	44*	4,4 3,9—5,0	2,92 (0,72—4,96)	Venous	44*	**2,1**	-0,5— 4,7	45*	**3,9**	3,2—4,9
	20		*0,72-3,00*	Venous	*20*	*-2,4*	*-5,2—0,3*			
	24		*3,01-4,96*	Venous	*24*	*6,3*	*4,6—8,0*			
Mean	46*	3,8 3,4—4,4	7,03 (5,07—9,0)	Venous	46*	7,6	6,2—9,0	47	**2,4**	2,1—2,7
High	46	2,9 2,6—3,3	28,2 (9,23—172)	Venous	46	7,0	4,8—9,2	46	**1,9**	1,7—2,2
All	136*	3,1 2,7—3,5	12,76 (0,72—172)	Venous	136*	**5,8**	4,6—7,0	138	**2,8**	2,5—3,2

	Chempaq, Total Error			
	Interval x 10^9/L	N	Deviation < ± 16% %	Deviation 95% within limits** %
Capillary	3,0—15,9	40	100	—
Venous	0,7—5,0	45	95,6	—
Venous	5,1—9,0	47	95,6	—
Venous	9,2—172	46	86,9	± 21,5%

adjusted for bias. Three samples were outside the interval 1-100 x 10 ^{9}/L. * One outlier (duplicates) and two outliers (deviation) according to Burnett. The results in bold fulfils the SKUP goals. The deviation is adjusted for the bias of Sysmex. **percentage limits for 95% of results.

Imprecision fulfils the quality specifications. The corrected estimates of bias seem to be acceptable according to the quality specifications for capillary samples. For the venous results only the lowest have a bias less than 6,6%.

5.5.2. *Primary care. Evaluation 1.*

Results

In GP A there were flags for leukocytes in one duplicate measurement in both the venous and capillary samples in one patient. There were also flags in the corresponding Sysmex results. In addition, there was flag in one of the duplicates in one capillary sample.

In GP B the seven first venous results were unintentionally not measured in duplicates. One sample for the comparison method was coagulated. In four samples Error 60 occurred. One capillary sample was not reported because the printer was off. There were flags in one of the duplicates in two venous sample and two capillary samples, in total, four samples. In a fifth sample Sysmex had flags in one of the duplicates.

Table 16. Leukocytes, Primary Care, Evaluation 1
Analytical imprecision (CV_{within}), Bias and Total Error, venous and capillary samples.

	Sysmex			Chempaq						
GP	N	Mean (range)	CV_{within} (95CI%)	Sample	N	Bias #	95 % CI	N	CV_{within}	95% CI
		LKC x 10 ^{9}/L	% %			%	%		%	%
A	39	8,08 (3,7 – 25,2)	*1,55(1,3 – 2,0)*	Capillary	38	8.1	5.6—10.6	38	5.8	4.7 – 7.5
				Venous	37	10.3	9.2—12.4	37	**2.4**	2.0 – 3.1
B	39	6,98 (3,2 – 12,0)	*1,46(1,2 – 1,9)*	Capillary	30	14.4	10.6—18.1	31	7.8	6.3 – 10.4
				Venous	31	10.9	8.8—13.0	31	**3.0**	2.4 – 4.0

Chempaq, Total Error					
		Interval x 10 ^{9}/L	N	Deviation < ± 16% %	Deviation 95% within limits** %
GP A	Capillary	3 – 15	39	79,5	22,5
	Venous		37	89,2	18
GP B	Capillary	3 – 12	33	54,5	35
	Venous		39	74,4	19

adjusted for bias. GP A, outliers, venous: no 13 and 37 were outliers in the duplicates. GP B, outliers, capillary: no 2 and 9 were outliers in the duplicates

Table 17. Leukocytes, Primary Care, Evaluation 1, First 20 samples versus last 20 samples.
Analytical imprecision (CV_{within}) and Bias, venous and capillary samples.

GP	Sample	sample no	N	Bias #	95 % CI	N	CV_{within}	95% CI
		LKC x 10 ^{9}/L		%	%		%	%
A	Capillary	1-20	18	6,6	3,5—9,6	19	6,7	5,1—10,0
		21-40	19	9,7	5,5—13,8	19	**4,7**	3,6—6,8

	Venous	1-20	18	10,1	7,9—12,3	18	**2,6**	2,0—3,8
		21-40	19	11,5	9,0—14,0	19	**2,3**	1,7-3,3
B	Capillary	1-20	14	14,6	7,4—21,8	13	9,3	6,7—15,5
		21-40	17	14,2	9,9—18,4	17	6,3	4,8—9,2
	Venous	1-20	12	10,5	7,0—13,9	12	**3,6**	2,6—5,9
		21-40	19	11,2	8,2—14,0	19	**2,5**	1,9—3,7

adjusted for a sysmex bias. The table demonstrate that the bias even if adjusted for the bias of Sysmex is too high. The imprecision tend to improve by practice in both primary care centres.

The table 17 also demonstrate that the adjusted estimates of bias are too high.

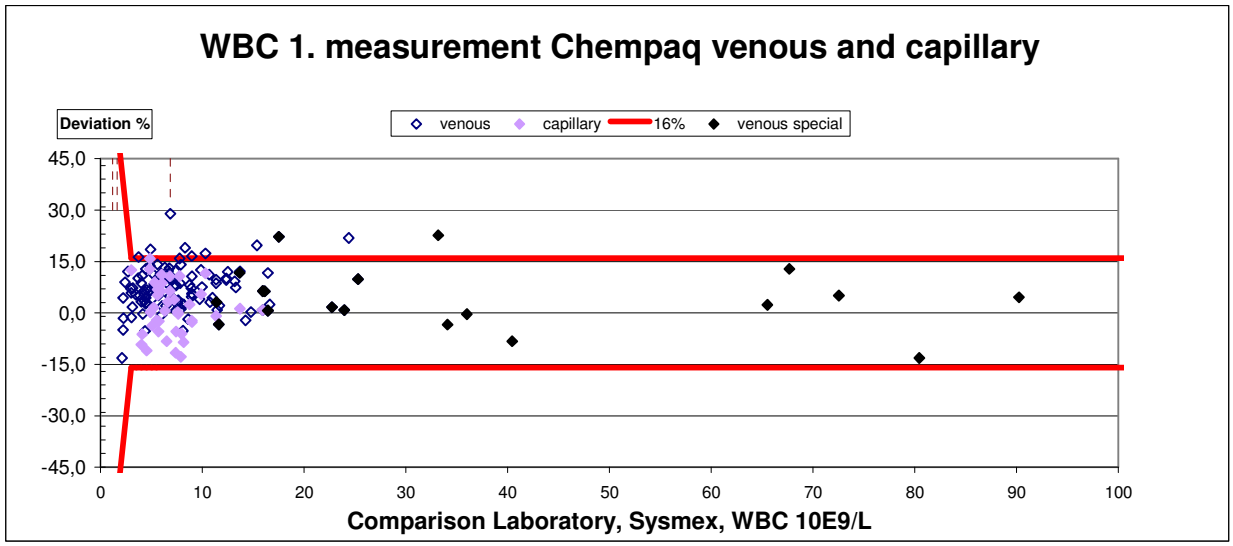
Repeatability

CV_{within} in venous samples was 2,4 and 3,0%, while CV_{within} in capillary was 5,8 and 7,8%; the goal of SKUP was 5,5%, while the expectation from the manufacturer was less than 5,0%.

The impression in primary care for the last 20 samples did not differ significantly from the imprecision achieved by the experienced laboratory technician.

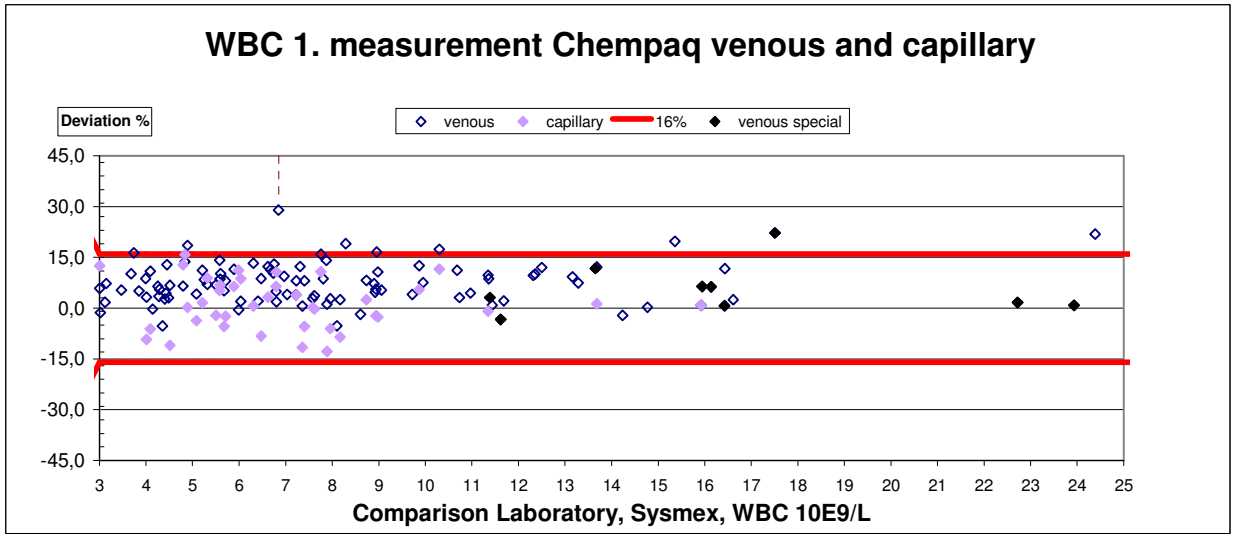
The imprecision for the comparison method was much better for samples from primary care evaluation 1 study than for samples from the hospital evaluation. This is due to the time span of minutes instead of hours between the repeated measurements.

Figure 14. Total Error. Hospital laboratory



The diagram shows the deviations of the Chempaq XBC results with capillary and venous samples. X-axis = mean of comparison method, duplicate results and Y-axis = ((first Chempaq XBC result– mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. Acceptance limits for Chempaq XBC is ± 16 % for concentration >3 x 10^9/L . Below this concentration a deviation of 100% is allowed. 95 % of the results should be within the acceptance limits. One outliers > 3 x 10^9/L according to Burnett. For concentrations of ≤3,0 x 10^9/L a deviation 100% was accepted.

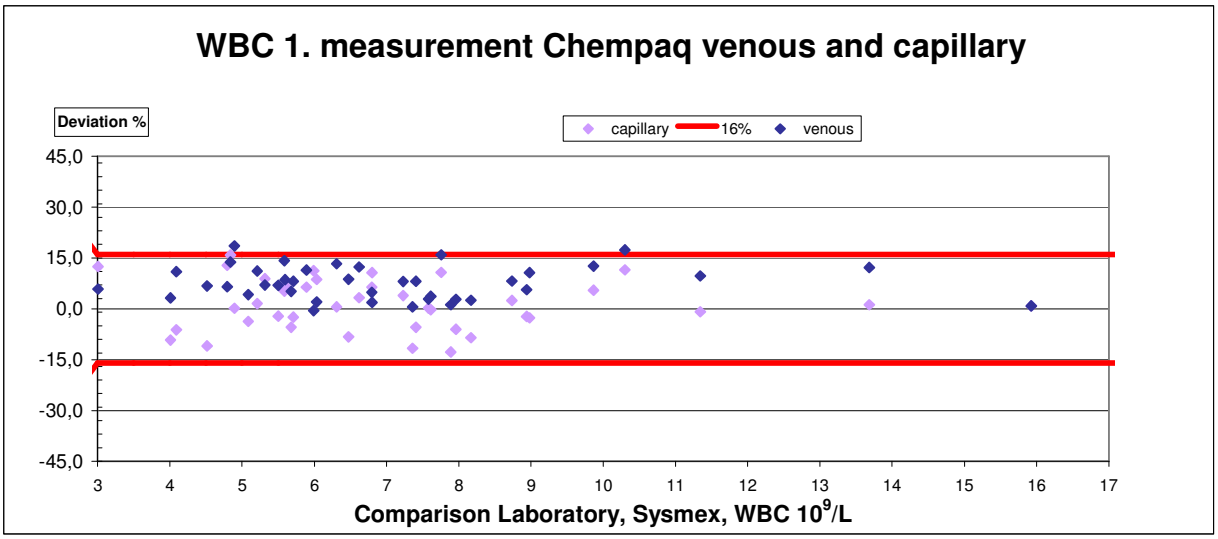
Figure 15. Total Error. LKC 3-25 x 10^9/L.



The figure 15 is the same as figure 14 just focusing on Leukocytes 3-25 x10^9/L. The results are adjusted for bias. For concentrations of ≤3,0 x 10^9/L a deviation 100% was accepted.

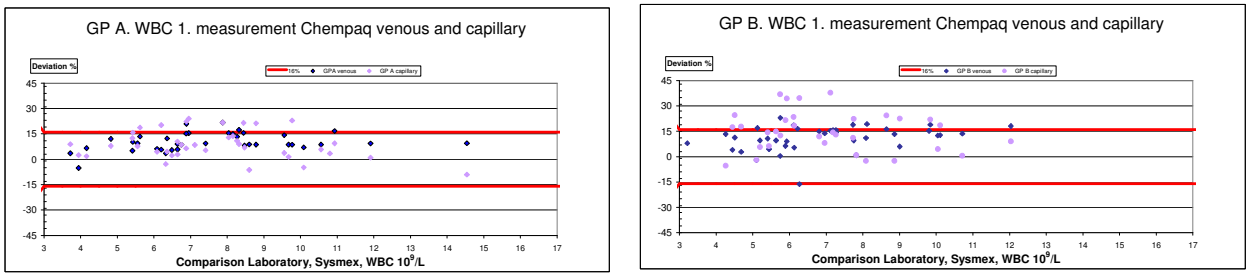
Leukocytes. Outpatients. Venous and capillary samples

Figure 16. Total Error. Hospital laboratory



40 random outpatients had taken both capillary and venous samples in the hospital. The figure demonstrates the results in the capillary and venous samples. Comparison method Sysmex adjusted for bias. For concentrations of ≤3,0 x 10^9/L a deviation 100% was accepted.

Figure 17 and 18. Total Error. Primary Care Evaluation 1.



The diagrams show the deviations of the Chempaq XBC results with capillary and venous samples in two General Practitioners laboratory adjusted for bias. X-axis = mean of comparison method, duplicate results, and Y-axis = deviation ((first Chempaq XBC result – mean of comparison method, duplicate results)/mean of comparison method, duplicate results x 100). Acceptance limits for SKUP is ± 16 %. 95 % of the results should be within the acceptance limits. For concentrations of ≤3,0 x 10^9/L a deviation 100% was accepted.

The figures demonstrates that the bias even after adjustment of the comparison method is more than 7%. The bias is the main reason for why the total error is above 16% in GP A.

In the Hospital evaluation the bias was most pronounced in the venous samples. In the primary health care evaluation, the bias was was the same for both venous and capillary samples.

5.6. Leukocytes, Primary care 2

Primary care. Evaluation 2, Imprecision (CV_{within}), Bias

In primary care evaluation 2 more than 70% belonged to range 5,1 to 11,0 x 10^9/L in the comparison method Coulter

Table 18. Leukocytes, Primary Care 2.

Analytical imprecision (CV_{within}) and Bias, venous and capillary samples.

	Sysmex			Chempaq						
GP	N	Mean (range)	CV_{within} (95CI%)	Sample	N	Bias	95 % CI	N	CV_{within}	95% CI
		Lkc x 10^9/L	% %			%	%		%%	%
A	39#	6,4 (3,8—10,3)	*1,06(0,4—1,4)*	Capillary	38	**1,7**	-0,1—3,5	39*	8,3	6,7—11,0
				Venous	31	**-0,1**	-1,9—1,6	32	**2,7**	2,2—3,6
B	42	7,0 (4,3—15)	*1,31(1,1—1.7)*	Capillary	41	**4,5**	1,0—8,1	41*	7,6	6,2—9,7

one sample excluded. * outlier according to Burnett. GP A had a high percentage of errors in the beginning and was asked also to measure venous samples.

Figure 19. Total Error. Primary Care Evaluation 2.

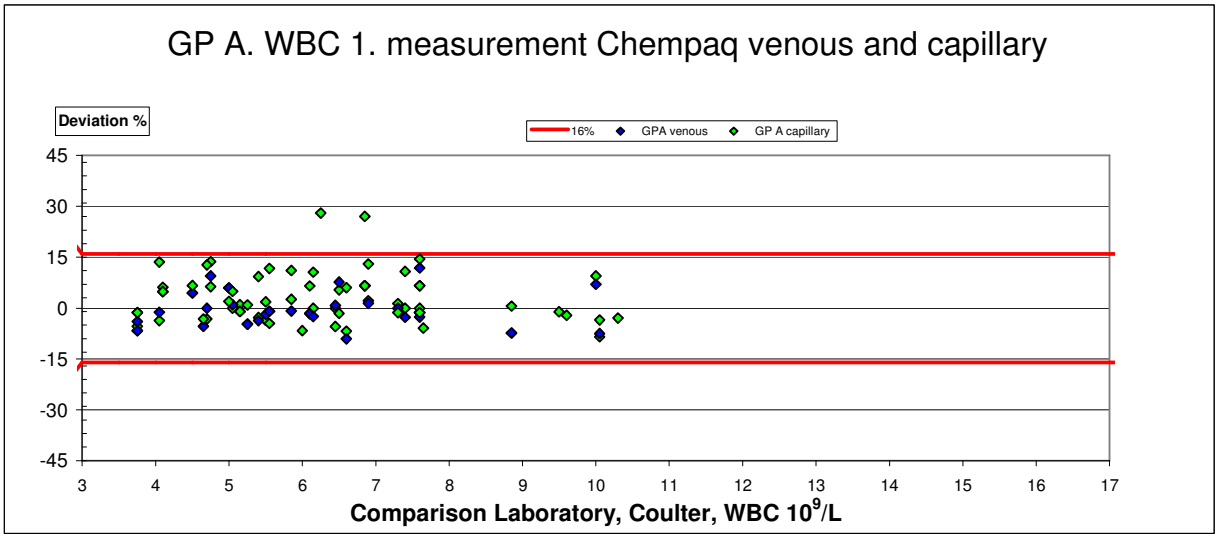
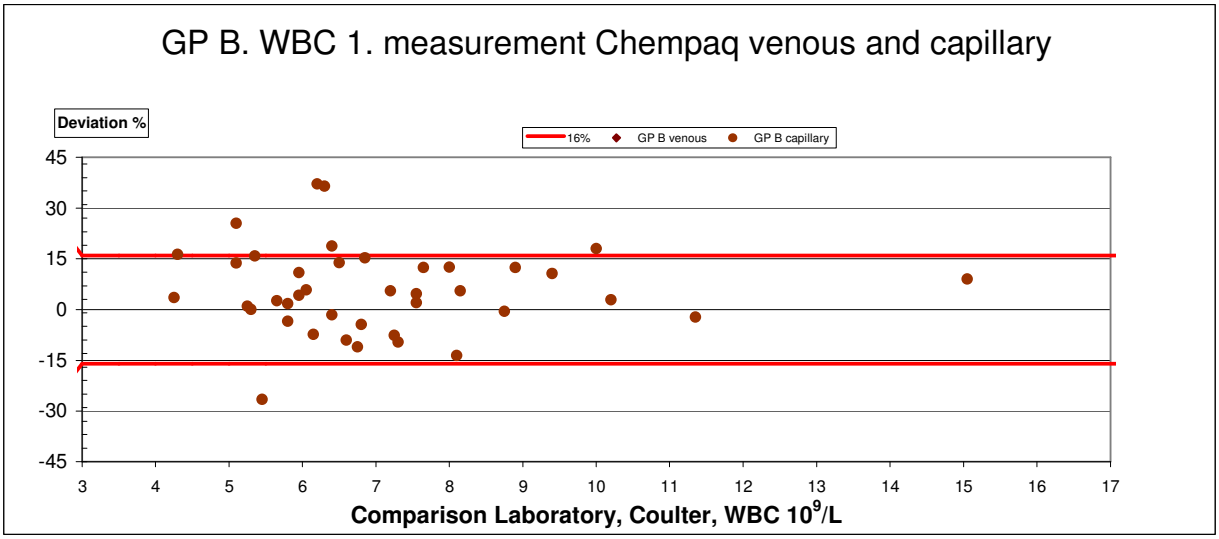


Figure 20. Total Error. Primary Care Evaluation 2.



The diagram in figure 19 and 20 shows the deviations of the Chempaq XBC results with capillary and venous samples in the two General Practitioners laboratory. X-axis = mean of comparison method, duplicate results, and Y-axis = ((first Chempaq XBC result – mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. Acceptance limits for SKUP is ± 16 %. 95 % of the results should be within the acceptance limits.

Table 19. Leukocytes, Outpatients. Hospital and Primary Care. Evaluation 2

	LKC	Interval LKC x 10 ^{9}/L	N	Deviation < ±16% %	Deviation 95% within limits* %
Hospital	Capillary samples	3,0—15,9	40	**100**	—
	Venous samples			**93**	17
GP A	Capillary samples	3,8—10,3	39	**94,7**	—
	Venous samples		32	**100**	—
GP B	Capillary samples	4,3—15	41	83,3	27

*percentage limits for 95% of results.

The purpose of evaluation 2 was to investigate if the bias was reduced to acceptable limits and to examine if imprecision also had improved by using a lot with no evaporation of the reagent. Lot 131 were used for all results. Only capillary samples should have been evaluated, but due to a high percentage of errors in GP A, SKUP asked GP A to add venous samples.

As seen in table 18 bias was reduced to acceptable levels (< 6.6%) in both capillary and venous samples. However the imprecision of the capillary samples was still above the expected goals of Chempaq and SKUP. The goal of a total error less than ±16% was achieved in GP A for both capillary and venous samples, but not for GP B were only 83% of the capillary results were within the 16%. This may be attributed to capillary sampling.

Conclusion Leukocytes

The results for leukocyte counts in the hospital laboratory performed by an experienced laboratory technologist did fulfil the quality goals for imprecision and total error for both venous and capillary samples.

The Bias of 10-14% in the first primary care evaluation was reduced to 0-4.5% in the second evaluation.

Chempaq XBC fulfilled the quality goals for leukocyte counts in venous samples in the two primary health care centres.

The goals for capillary samples were fulfilled in one of the two primary health care centres. In the other centre only 83% of the capillary samples were within ±16% of the comparison method. This was due to a positive bias of about 4.5% combined with an imprecision of 7.6%. In both primary health care centres the imprecision was significantly better in venous samples than in capillary samples, this may be attributed to capillary sampling. According to both primary care centres the application of the especially the capillary samples was difficult.

5.7. Three part differential, Hospital and Primary Care 1

40 Random out patients: The first patients were chosen randomly for Capillary samples analysed in duplicates in Chempaq XBC. A corresponding venous sample was also measured in duplicate in Chempaq XBC and Sysmex SE 9000. In total there were remarks to 5 samples. Only one of the 80 capillary and one of the venous results in Chempaq was marked (1 of 80, (1,25%)) while 2 of the 40 Sysmex SE 9000 samples had the remark 'immature'? in both duplicates and one had a technical error in one result (6,3%). All samples were normal when seen in microscope.

59 Selected outpatients: The latest out patients included were chosen due to their values in Haemoglobin or Leukocytes after table 2, which mean that more remarks were expected to occur.

The 43 hospitalised patients had samples chosen after table 3. Three results were out of range (1-100 x 10^9/L) for Chempaq, they all gave remarks in duplicate with Sysmex SE 9000.

In table 20 the discrepancies are shown, including the capillary remarks. For 7 samples out of 142 the routine result indicated that the differential contained immature cells (2), specified as metamyelocyts (2), myelocyts (5), promyelocyts (2) or blasts (1). The finding of 'blasts' was not obvious from the treatment and the diagnosis of the patients.

3-part differentials (Chempaq) 5-part differential (Sysmex)

Chempaq classifies cells into Granulocytes (GR), Monocytes (MO) and Lymphocytes, (LY). Sysmex classifies the leukocytes into 5 cell classes. The GR from Chempaq XBC was compared with the sum of baso-, eosino-, and neutrophilocytes from Sysmex.

A single remark, or 'flag', in one of the two pairs of duplicates disqualified the results to be used for calculation of bias. For imprecision the duplicate results is mandatory. For total error only the first result for the Chempaq XBC is used and the duplicate of the comparison method.

For the samples from hospital there was good agreement between Chempaq and Sysmex SE 9000. For the samples from primary health care only a few had remarks in Chempaq or the comparison methods. See table 20, 25 and 30 and enclosure E for raw data.

In the Sysmex SE 9000 method there could be remarks to Leukocytes and/or the 5 part in the differential count. Either message trigger a decision if the result should give rise to a manual count with microscope, or not? If a manual count by a technologist were not deemed necessary, it was called 'automatically count', if no result from a sample had remark the result was called 'normal'. (see Enclosure C).

Table 20. Summary of 'Flags' for Chempaq and Sysmex SE 9000 for 142 samples.

	Sysmex SE 9000 remarks in both duplicates	Sysmex SE 9000 remarks in one of the duplicates	Sysmex SE 9000 no remarks
Chempaq remarks in both duplicates	18	0	2
Chempaq remarks in one of the duplicates	2 *(2 some remarks)*	2	4
Chempaq no remarks	16 *(5 some remarks)*	6	93

Grey area: results of ordinary instrumental or manual differential. When 'normal', no immature cells as metamyelocyts, myelocyts, promyelocyts or blasts were seen. 'some remarks' cover that at least one of these groups is seen. * In total there were 142 samples. 3 were chosen due to the high or low haemoglobin and had no ordinary diff.

For 111 (18 plus 93 duplicate results) of the 142 samples the two instruments agreed that a manual differential counting should or should not be performed.

For 32 samples there were discrepancies between the instruments in one or two of the duplicate samples. In 23 samples the automatically or the manual count was 'normal' except for 'band neutrocyts', while two samples had 'atypical lymphocytes'. For 7 samples the routine result in duplicate indicated that the differential contained immature cells (2), specified as metamyelocyts (2), myelocyts (5), promyelocyts (2) or blasts (1). The finding of 'blasts' were not obvious from the treatment and the diagnosis of the patients. In the corresponding Chempaq samples two results had remarks in one of the duplicates.

'Flags' resulting in manual differential in Sysmex SE 9000: See enclosure C

'Flags' in the three groups of patients in the material:

Table 21. Discrepancies

	Chempaq								Sysmex							
	WBC	LY	MO	GR	Hgb	LY%	MO%	GR%	WBC	LY	MO	GR	Hgb	LY%	MO%	GR%
no.																
1138	8,0	3,6	0,8	3,7	5,3	44,4	9,8	45,7	7,8	3,5	1,0	3,1	5,2	44,8	12,9	42,3
	8,4	3,7	0,8	3,9	5,4	43,3	9,8	46,8	8,4	4,4	0,8	3,1	5,3	52,0	9,1	38,9
1125	42,0	32,4	5,5	4,1	6,7	77,1	13,0	9,9	31,7	26,5	1,5	3,3	6,6	83,7	4,9	11,4
	41,7	32,7	5,4	3,6	6,7	78,5	12,9	8,6	34,7	1,5		0,3	6,5	4,4		
1120	1,4	0,5	0,1	0,8	7,5	34,3	9,7	55,9	1,4	0,3	0,5	0,5	7,3	21,7	33,6	44,8
	1,5	0,5	0,1	0,9	7,4	33,1	9,6	57,3	1,5	0,3	0,4	0,7	7,3	18,3	27,5	43,8
1103	11,1	0,5	0,4	10,3	8,9	4,1	3,3	92,6	9,9	0,4	0,7	8,7	8,7	3,9	7,4	88,7
	11,0	0,4	0,3	10,2	8,8	3,7	3,0	93,3	10,0	0,4	0,5	8,9	8,7	4,4	5,2	89,0
1143	1,9	0,3	0,1	1,4	7,6	16,6	6,6	76,8	2,0	0,2	0,1	1,5	7,3	11,1	6,6	82,3
	2,0	0,3	0,1	1,5	7,7	16,4	6,2	77,3	2,2	0,9			7,2	40,9		
1133	17,6	2,4	0,7	14,5	7,7	13,6	4,2	82,2	15,9	2,0	1,2	12,5	7,5	12,7	7,8	79,1
	16,9	2,5	0,8	13,5	7,6	15,1	4,6	80,3	16,0	2,1	1,3	12,6	7,5	13,0	8,0	78,4
1130	15,8	6,1	1,7	8,0	6,7	38,6	11,0	50,4	13,3	6,1			6,6	45,6		
	15,9	6,3	1,7	7,8	6,8	39,8	11,0	49,2	14,1	7,1	1,0	6,0	6,6	50,4	6,8	
1135	69,7	15,3	6,2	48,2	6,6	22,0	8,9	69,2	65,4	14,5			6,0	22,2		
	69,9	12,2	5,4	52,3	6,8	17,5	7,7	74,8	65,7	2,0			6,1	3,0		
1139	98,0	12,9	7,1	78,0	5,0	13,1	7,3	79,6	86,7	2,1			4,5	2,4		
	98,8	13,8	7,3	77,7	5,1	14,0	7,4	78,6	93,8	1,7			4,5	1,8		
1114	3,3	0,6	0,3	2,3	5,3	19,8	10,0	70,2	2,9	0,4	0,9	1,5	5,2	12,5	30,9	56,6
	3,0	0,6	0,3	2,1	5,3	20,8	9,2	70,1	3,4	0,5	0,4	2,3	5,2	16,1	11,0	72,9
1097	12,3	2,4	0,9	9,0	11,5	19,8	7,2	73,0	10,6	2,8	0,5	6,7	11,1	26,6	5,0	68,4
	12,2	2,2	0,8	9,1	11,5	18,0	6,8	75,2	10,7	2,5	0,6	7,1	11,1	23,7	5,6	70,7
1136	17,2	2,5	1,1	13,6	4,5	14,7	6,1	79,2	16,2	1,8	0,8	13,5	4,4	11,1	4,8	84,2
	18,2	2,7	1,2	14,4	4,8	14,8	6,4	78,8	16,7	2,0	0,8	13,8	4,4	12,0	4,7	83,3

The coloured numbers have remarks. The first 7 samples were the ones that had the discrepancies between Chempaq and Sysmex SE 9000 and the manual count. They all come from hospitalised patients. No 1135 and 1139 are from the same patient as no. 1130 after 21 and 24 days, respectively. It was repeated because of the discrepancies. However the two last samples had remarks in duplicate in both Chempaq and Sysmex SE 9000. For the last three samples there are no routine counting, they were chosen due to the haemoglobin values. The remarks in Sysmex SE 9000 were 'blasts?' for 1114 and 1136, 'immature granulocytes?' for 1114 and 'abnormal lymphocytes?' for 1097.

Results

The percentage of Granulocytes, Lymphocytes and Monocytes are not influenced of the bias in Leukocytes, while the total number concentration is. See example:

	Comparison method		Tested method	
LKC	10 x 10^9/L		20 x 10^9/L	
GR	5 x 10^9/L	~ 50%	10 x 10^9/L	~ 50%
LY	4 x 10^9/L	~ 40%	8 x 10^9/L	~ 40%
MO	1 x 10^9/L	~ 10%	2 x 10^9/L	~ 10%

For Primary Care Evaluation 1 only the results for bias and imprecision are shown in tables.

For the Hospital testing the imprecision in Sysmex SE 9000 was higher than in the primary care testing, this was due to the time span between the samples of up to an average of 211 minutes. In the Primary care testing the duplicate measurements were performed within a few minutes.

Analytical quality Three part differential

5.7.1. *Hospital Laboratory, CV_{within}, Bias*

See general comments Leukocytes. The samples excluded for Leukocytes are not used in the results for the three part differential.

Table 22. Granulocytes (GR), Hospital Laboratory, Chempaq XBC
Analytical imprecision (CV_{within}) and Bias, venous and capillary samples.

	Sysmex SE 9000			Chempaq						
	N	GR (range) x 10^9/L	CV_{within} (95CI%) % %	Sample	N	Bias # %	95 % CI %	N	CV_{within} %	95% CI %
Outpatients	37	2,4 – 11	6,8(5,6 – 8,8)	Capillary	35	9,4	7,5 – 12,8	37	**5,7**	4,7 – 7,3
				Venous	37	16,8	13,4 – 20,3	37	**3,4**	2,9 – 4,5
Granulocytes > 2,0 x 10^9/L										
Selected patients	43	2,0 – 13,8	6,2(5,1 – 7,9)	Venous	37	16,8	13,3 – 20,1	57	**5,8**	4,9 – 7,1

The results in bold fulfils the quality goals of SKUP. GR, Sysmex SE 9000 = Neutro-, Eosino-, basophilocytes x 10^9/L.

Table 23. Lymphocytes (LY), Hospital Laboratory, Chempaq XBC
Analytical imprecision (CV_{within}) and Bias, venous and capillary samples.

	Sysmex SE 9000			Chempaq						
	N	GR (range) x 10^9/L	CV_{within} (95CI%) % %	Sample	N	Bias # %	95 % CI %	N	CV_{within} %	95% CI %
Outpatients	37	2,4 – 11	6,8(5,6 – 8,8)	Capillary	35	**-2,0**	-5,7 – -1,8	38	7,6	6,2—9,8
				Venous	36	**-7,1**	-10,9 – -3,2	39	6,3	5,2—8,1
ymphocytes > 0,3 x 10^9/L										
Selected patients	62	0,3 – 15,0	9,2(7,8 – 11,2)	Venous	54	**5,8**	0,9 – 10,7	76	6,9	(6,0—8,2)

The results in bold fulfils the quality goals of SKUP. The goal of Chempaq for CV-analytical < 13% was fulfilled.

Table 24 Monocytes (MO), Hospital Laboratory, Chempaq XBC
Analytical imprecision (CV_{within}) and Bias, venous and capillary samples.

	Sysmex SE 9000			Chempaq						
	N	GR (range) x 10^9/L	CV_{within} (95CI%) % %	Sample	N	Bias # %	95 % CI %	N	CV_{within} %	95% CI %
Outpatients	37	0,2 – 1,4	15,4 (13 – 20)	Capillary		**-3,9**	-13 – 5,3	38	**9,5**	7,8 – 12,2
				Venous				38	**8,0**	6,6 – 10,4
Monocytes > 0,1 x 10^9/L										
Selected patients	62	0,2 – 4,1	15,6 (13 – 19)	Venous				76	**9,7**	8,3 – 11,5

The results in bold fulfils the quality goals of SKUP.

The imprecision in Sysmex SE 9000 in hospital was higher than expected for all three components in the differential, it was also higher than the imprecision in Chempaq. We allowed the time span between duplicates to be higher than recommended [18,19] (table 22-24) and it is demonstrated (table 26-28) that when the timespan in Sysmex SE 9000 duplicates is almost the same as between the Chempaq duplicates the imprecision is much better.

5.7.3. *Primary care. CV_{within}, Bias. Evaluation 1.*

Results

Table 25. 'Flags' for Chempaq and Sysmex

	Sysmex SE 9000 remarks in both duplicates	Sysmex SE 9000 remarks in one of the duplicates	Sysmex SE 9000 no remarks
Chempaq remarks in both duplicates	1 (venous and capillary)	0	0
Chempaq remarks in one of the duplicates	0	0	1 venous and 2 capillary
Chempaq no remarks	0	1	75 capillary results 76 venous results

* one Sysmex SE 9000 sample was not analysed due to coagulation.

Table 26. Granulocytes, Primary Care, Evaluation 1
Analytical imprecision (CV_{within}) and Bias, venous and capillary samples.

	Sysmex SE 9000			Chempaq						
GP	N	Mean (range)	CV_{within} (95CI%)	Sample	N	Bias	95 % CI	N	CV_{within}	95% CI
	x 10^9/L		% %			%	%		%%	%
A	39	5,03 (2,1 – 10.6)	*2,7 (2,2 – 3,5)*	Capillary	38	17	13 – 21	38	**6,6**	5,4 – 8,6
				Venous	37	24	21 – 28	37	**4,3**	3,6 – 5,5
B	38	4,69 (1,7 – 9.2)	*3,2 (2,6 – 4,3)*	Capillary	28	25	21 – 29	30	8,5	6,8 – 11,3
				Venous	31	23	20 – 27	31	**4,9**	4,0 – 6,6

The results in bold fulfils the quality goals

Table 27. Lymphocytes, Primary Care, Evaluation 1
Analytical imprecision (CV_{within}) and Bias, venous and capillary samples.

	Sysmex SE 9000			Chempaq						
GP	N	Mean (range)	CV_{within} (95CI%)	Sample	N	Bias	95 % CI	N	CV_{within}	95% CI
	x 10^9/L		% %			%	%		%%	%
A	39	2,3 (0,6 – 14,9)	*3,6 (2,9 – 4,6)*	Capillary	38	**1,7**	-1,6 – 5,1	38	7,0	5,8 – 9,2
				Venous	37	**-4,0**	-6,9 – 1,2	37	7,7	6,3 – 9,9

B	38	1,8 (0,7 – 3,7)	*4,2 (3,4 – 5,6)*	Capillary	31	**2,7**	-3,4 – 8,7	30	8,4	6,7 – 11,2
				Venous	31	**-3,1**	-7,4 to 1,3	31	6,2	5,0—8,2

The results in bold fulfils the quality goals

Table 28 Monocytes, Primary Care, Evaluation 1

Analytical imprecision (CV_{within}) and Bias, venous and capillary samples.

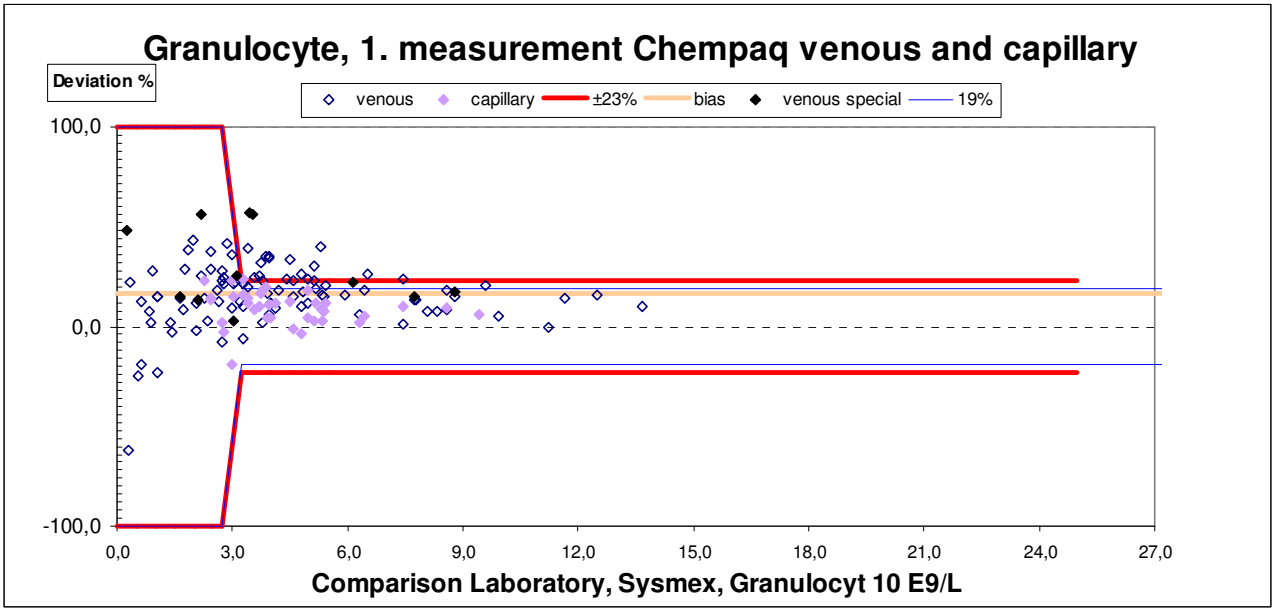
	Sysmex SE 9000			Chempaq						
GP	N	Mean (range)	CV_{within} (95CI%)	Sample	N	Bias	95 % CI	N	CV_{within}	95% CI
		x 10^9/L	% %			%	%		%	%
A	39	0,68 (0,2 – 4,0)	*7,4 (6,1 – 9,6)*	Capillary	38	**17**	7 – 26	38	13,7	11,2 – 17,7
				Venous	37	**17**	7 – 26	37	10,2	8,3 – 13,2
B	38	0,53 (0,2 – 1,2)	*7,7 (6,2 – 10,3)*	Capillary	31	28	15 – 41	31	13,4	10,8 – 17,9
				Venous	31	**19**	8 – 31	31	10,3	8,3 – 13,8

The results in bold fulfils the quality goals Outliers, Leukocytes, venous: GP A, no 13 and 37, GP B, Leukocytes capillary: no 2 and 9 were outliers in the duplicates.

Three part differential

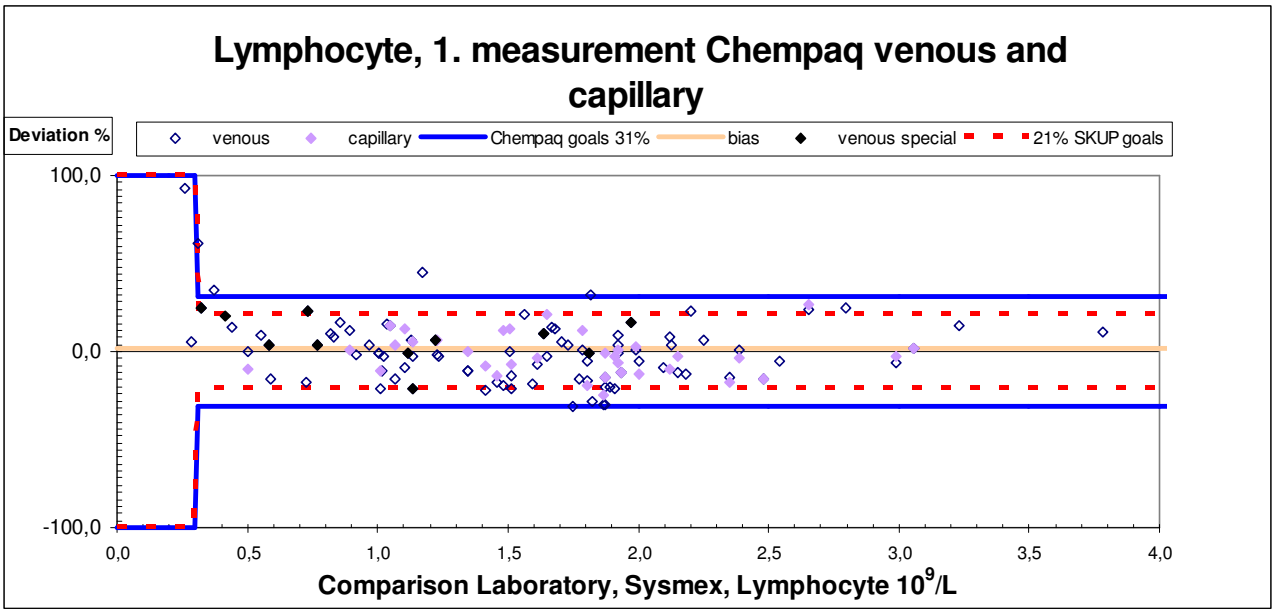
Total Error, Hospital Laboratory,

Figure 21. Granulocytes.



The diagram shows the deviations of the Chempaq XBC results with capillary and venous samples. X-axis = mean of comparison method, duplicate results and Y-axis = ((first Chempaq XBC result– mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. 95 % of the results should be within the acceptance limits. Acceptance limits of SKUP is ± 23 % (hatched red lines). (Chempaq expected ± 19%, blue lines) For concentrations of ≤3,0 x 10^9/L a deviation 100% was accepted.

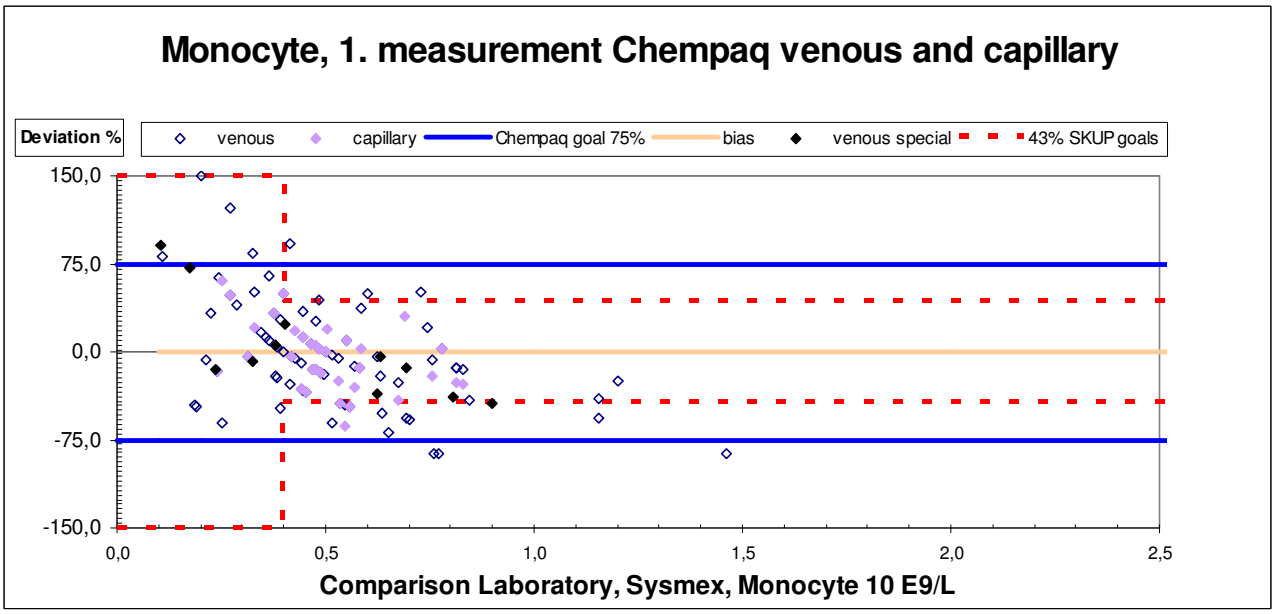
Figure 22. **Lymphocytes.**



The diagram shows the deviations of the Chempaq XBC results with capillary and venous samples. X-axis = mean of comparison method, duplicate results and Y-axis = ((first Chempaq XBC result– mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. 95 % of the results should be within the acceptance limits. Acceptance limits of SKUP is ± 21 % (hatched red lines lines). (Chempaq expected ± 31%, blue lines) For concentrations of ≤0,3 x 10^9/L a deviation 100% was accepted.
Below 0,3 x 10E9/L 100% was accepted

Figure 22 demonstrate that a Total Error of less than 21% is almost achieved for Lymphocytes in Chempaq compared to Sysmex SE 9000. The goal of Chempaq (31%) was achieved.

Figure 23. Monocytes.



The diagram shows the deviations of the Chempaq XBC results with capillary and venous samples. X-axis = mean of comparison method, duplicate results and Y-axis = ((first Chempaq XBC result– mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. 95 % of the results should be within the acceptance limits. Acceptance limits of SKUP is ± 43 % (hached red lines. (Chempaq expected ± 66%, blue lines). For concentrations of ≤0,4 x 10^9/L a deviation 150% was accepted.

Eosinophilocytes

Chempaq XBC does not separately quantify eosinofiles. It was not known if the eosinophilocytes and basophilocytes were measured as neutrophilocytes, monocytes or lymphocytes. Even with the bias in the Evaluation 1 it was demonstrated that this subpopulation is included in the quantification of granulocytes. There were no remarks on the samples with eosinofilocytes > 10% or > 40%. This means that the Chempaq XBC cannot be used for allergic purposes.

Table 29. 'Flags' and proportion of eosinophilocytes

% of eosinophils in Sysmex SE 9000 duplicates	Number	No remarks	Remark in one of the duplicates	Remarks in both duplicates
1-1,99	33	27	3	3
2-2,99	19	17	1	1
3,0-3,99	10	8	2	0
4,0-4,99	10	10	0	0
5,0-7,99	13	11	0	2
8,0-29,5	13	13	0	0

Figure 24. Samples with large proportion of eosinophilocytes.

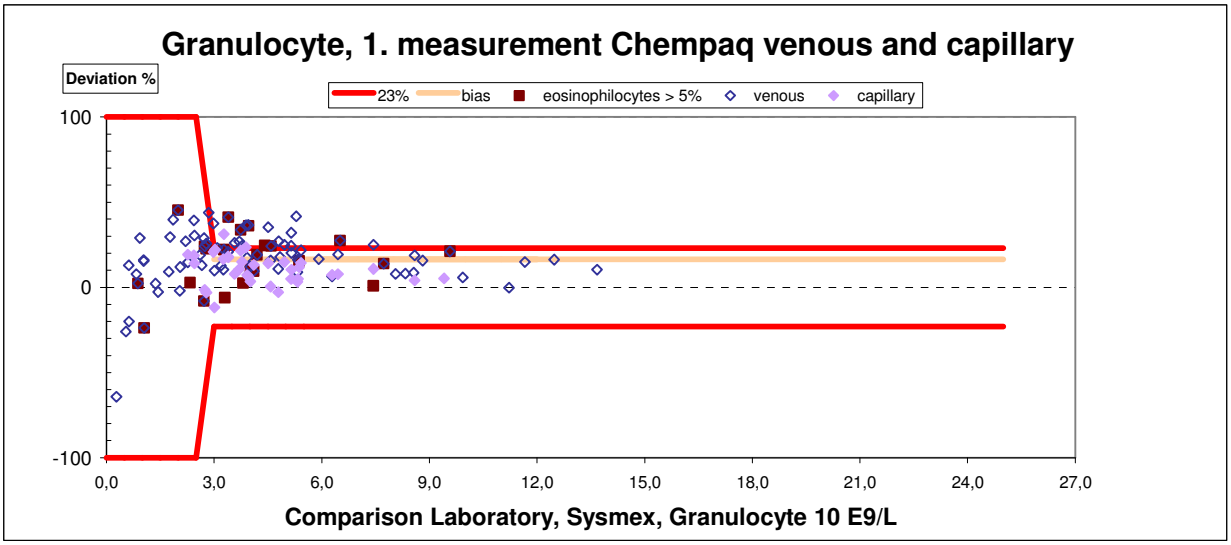


Figure 24 illustrates the distribution of the samples that had more than 5% of eosinophiles (brown squares). They do not differ from the results with low concentration of eosinophilocytes.

Figure 25. Samples with large proportion of eosinophilocytes.

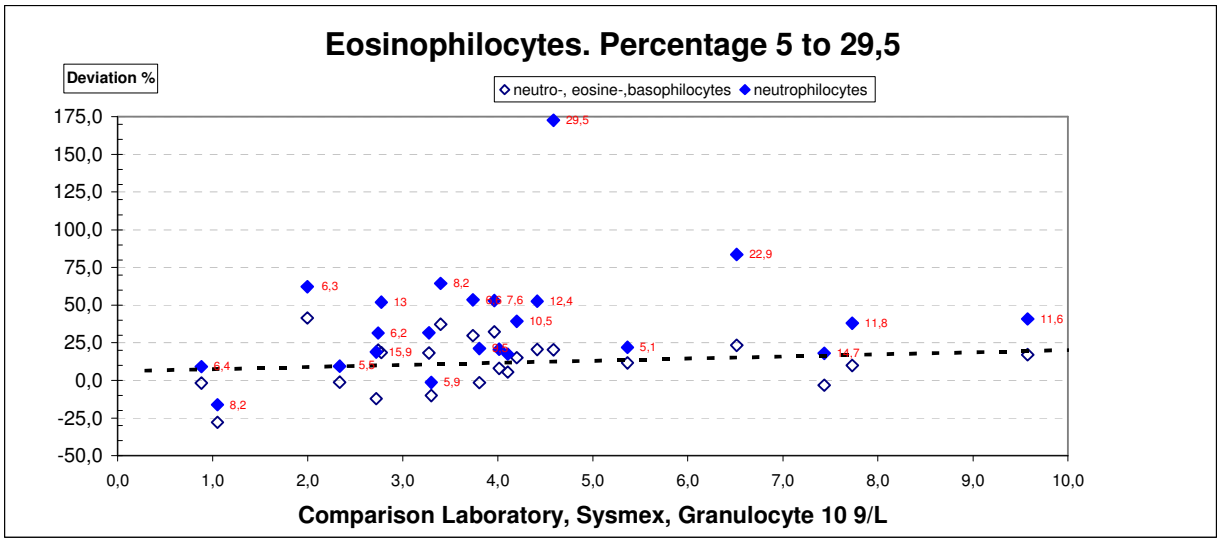


Figure 25 illustrates the deviation between Chempaq granulocytes and the distribution of the deviation for granulocytes (neutrophilocytes + eosinophilocytes+ basophilocytes) and the deviation of the same samples for neutrophiles for all the samples that had more than 5% of eosinophiles. The percentage of the eosinofilocytes in the Sysmex SE 9000 differential counting is marked for the deviation in which they are not included.

If eosinophiles were measured as monocytes or lymphocytes, the deviation of the samples with high content of eosinophilocytes would deviate from Sysmex SE 9000 as shown I figure 25 (closed symbols). However, the deviation (open symbols, dotted line) did not differ from the samples with less than 5% of eosinophiles.

Basophilocytes

18 of the samples had a mean percent of basophile between 1,0 and 9,1% as measured by Sysmex SE 9000. Of these 36 results from Chempaq XBC, there were only remarks in 2.

Lymphocytes, variant forms ('Atypical Lymphocytes')

Four patients (1041, 1063, 1066 and 1100) had positive test for heterophile antibodies (Mononucleosis infectiosa). Half of them had comments in the Sysmex SE 9000 results and more than 10 % variant forms of lymphocytes in the manual diff. There was no remark to any of the samples in Chempaq XBC.

5.8. 3-part differential, Primary care 2

Results

Table 30. 'Flags' for Chempaq and Coulter

	Coulter remarks in both duplicates	Coulter remarks in one of the duplicates	Coulter no remarks
Chempaq remarks in both duplicates	0	0	0
Chempaq remarks in one of the duplicates	0	0	0
Chempaq no remarks	0	0	79 capillary samples 32 venous samples

* one coulter sample was analysed after 23 hours. There were 14% of error codes in Chempaq.

Primary care. Evaluation 2, Imprecision (CV_{within}), Bias

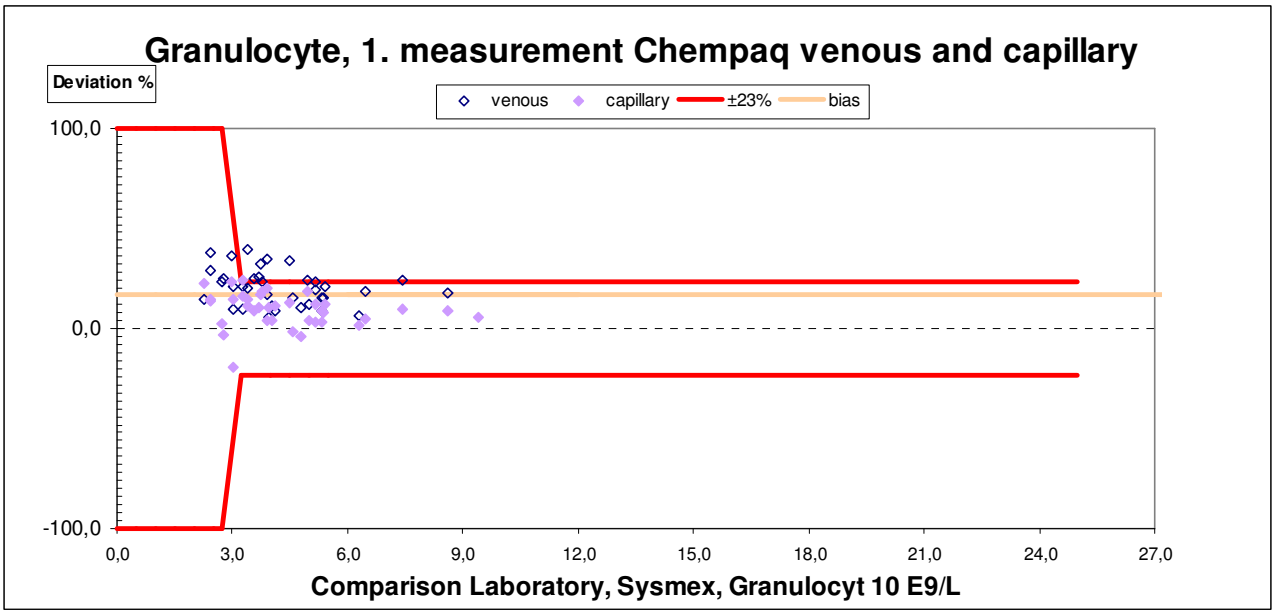
Table 31. Granulocytes

Analytical imprecision (CV_{within}) and Bias, venous and capillary samples.

	Coulter			Chempaq						
GP	N	Mean (range)	CV_{within} (95CI%)	Sample	N	Bias	95 % CI	N	CV_{within}	95% CI
		Neutrophilocytes eosiniphilocytes baosphilocytes x 10^9/L	% %	GR x 10^9/L		Granulocytes %	%		Granulocytes %	%
A	39#	4,0 (1,9 – 8,75)	*1,9(1,5 – 2,5)*	Capillary	39	**5,8**	2,7 – 8,9	39	9,8	7,9 – 13,0
				Venous	31	**4,6**	1,0 – 8,2	31	**5,9**	4,8 – 7,8
B	42	4,6 (2,4 – 11,9)	*2,3(1,9 – 3,0)*	Capillary	41	**1,7**	-1,9 – -5,4	40	8,7	7,1 – 11,1
	Coulter			Chempaq						
		%		GR %						
A	39#	60,7 (42 – 85)	*1,7(1,4 – 2,3)*	Capillary	40	**3,7**	1,4 – 6,0	39	**4,2**	3,4 – 5,6
				Venous	32	**4,3**	1,6 – 6,9	32	**3,8**	3,1 – 5,1
B	42	64,5 (43 – 86)	*1,0(0,9 – 1,3)*	Capillary	40	**-2,5**	-4,2 – -0,8	40	**3,5**	2,9 – 4,5

one sample excluded. * outlier according to Burnett. The results in bold fulfils the quality goals. GP A had a high percentage of errors in the beginning and was asked also to measure venous samples.

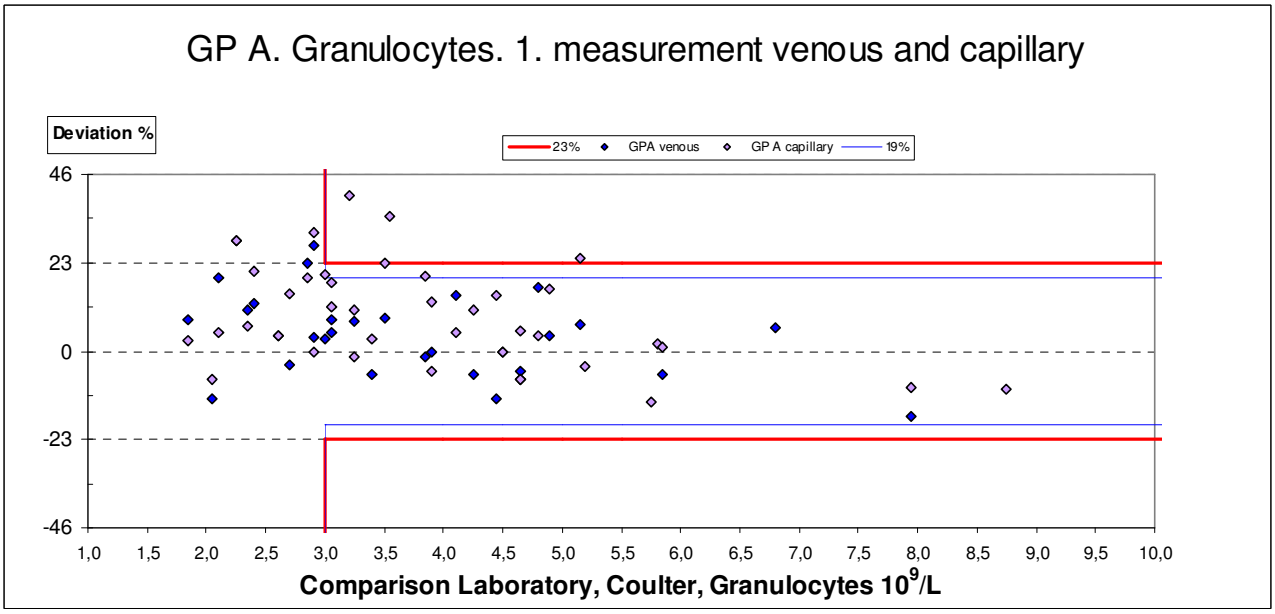
Figure 26. Granulocytes x 10^9/L. Total Error. Hospital outpatients.



The diagram shows the deviations of the Chempaq XBC results with capillary and venous samples. X-axis = mean of comparison method, duplicate results and Y-axis = ((first Chempaq XBC result– mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. 95 % of the results should be within the acceptance limits. Acceptance limits of SKUP is ± 23 %. (Chempaq expected ± 19%) For concentrations of ≤3,0 x 10^9/L a deviation 100% was allowed.

Figure 26 demonstrate that there was difference in venous and capillary results from the same patient for the hospital patients. A Total Error of less than 23% was achieved for capillary samples in the hospital, but not for venous samples.

Figure 27. Granulocytes x 10^9/L. Total Error. Primary Care.

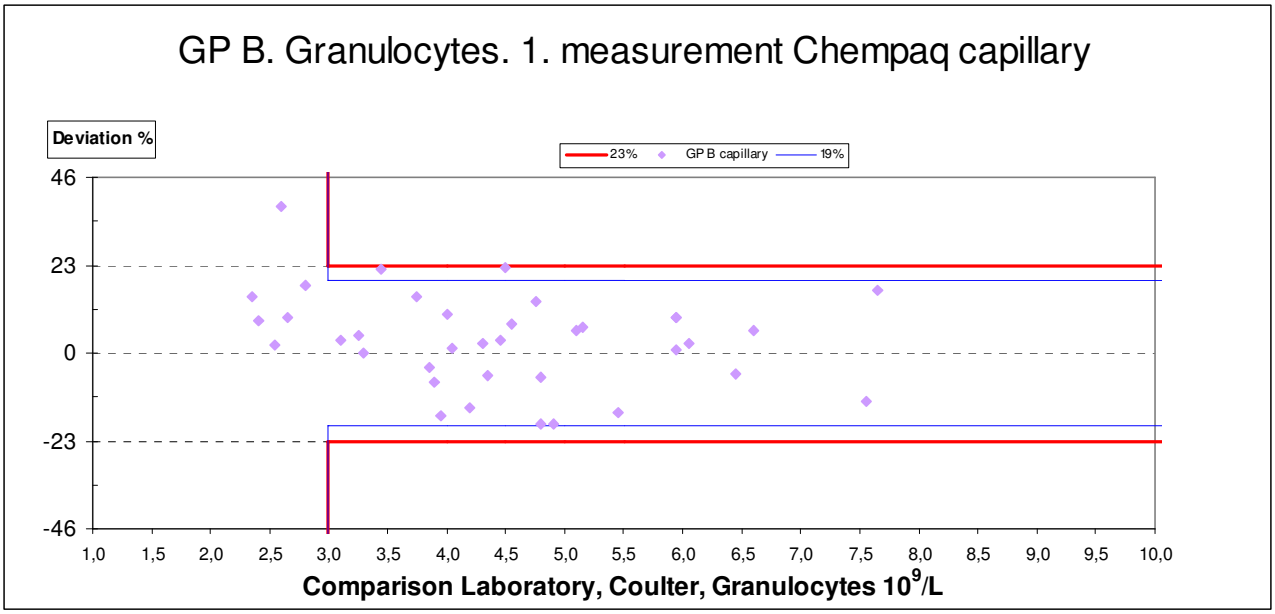


The diagram shows the deviations of the Chempaq XBC results with capillary and venous samples. X-axis = mean of comparison method, duplicate results and Y-axis = ((first Chempaq XBC result– mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. 95 % of the results should be within the acceptance limits. Acceptance limits of SKUP is ± 23 %. (Chempaq expected ± 19%). For concentrations of ≤3,0 x 10^9/L a deviation 100% was accepted.

In Primary care centre A the goal of SKUP was reached for the venous samples and capillary samples.

Figure 27 cannot demonstrate a difference in venous and capillary results from the same patient in primary care.

Figure 28. Granulocytes. Total Error. Primary Care.



The diagram shows the deviations of the Chempaq XBC results with capillary and venous samples. X-axis = mean of comparison method, duplicate results and Y-axis = ((first Chempaq XBC result– mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. 95 % of the results should be within the acceptance limits. Acceptance limits of SKUP is ± 23 %. (Chempaq expected ± 19%) For concentrations of ≤3,0 x 10^9/L a deviation 100% was allowed.

In Primary care centre B the goal of SKUP was reached for capillary samples.

Table 32. Total Error. Granulocytes, Outpatients. Hospital and Primary Care

Chempaq used in	Granulocytes	Interval GR x 10^9/L	N	Deviation < ±23%	Deviation 95% within limits* %
Hospital	Capillary samples	2,2 – 9,4	37	**94,6**	—
	Venous samples		36	88,9	—
GP A	Capillary samples	1,9 – 8,75	39	95	
	Venous samples		32	>95	
GP B	Capillary samples	2,4 – 11,9	41	**97,5**	—
		GR %			
GP A	Capillary samples	42 – 86	40	**100**	—
	Venous samples		32	**96,8**	—
GP B	Capillary samples	43 – 86	40	**100**	—

*percentage limits for 95% of results. The results in bold fulfils the quality goals.

For the interval > 3,0 x 10^9/L the total error less than 23% is fulfilled for both primary care centres but only for the capillary samples in hospital.

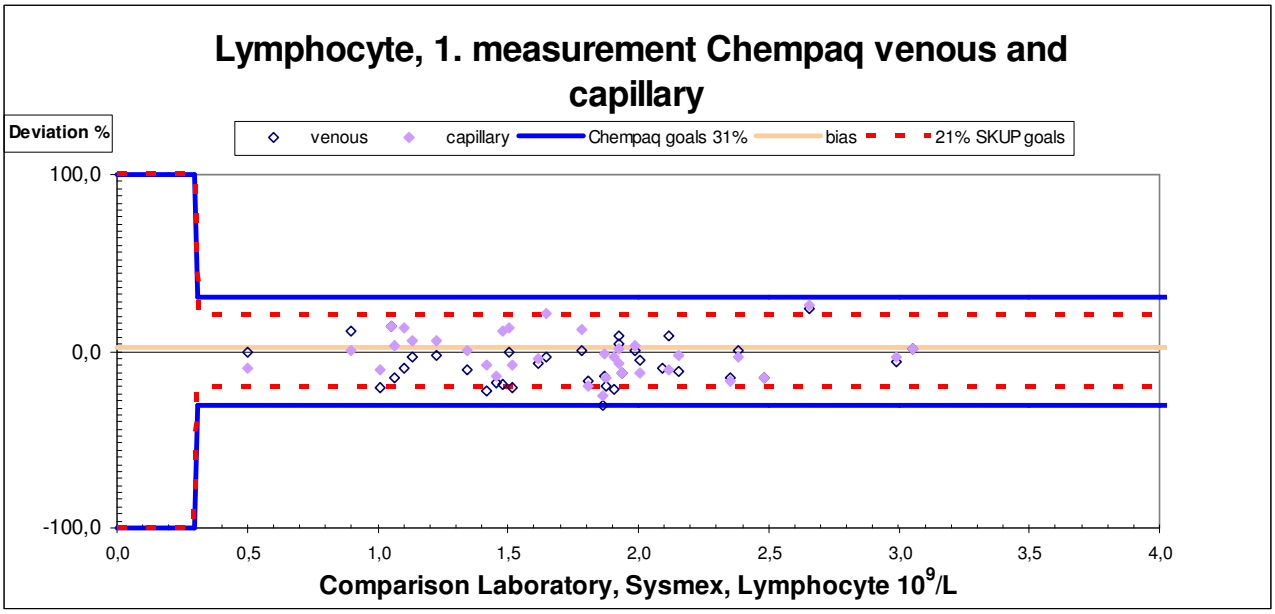
The discrepency between venous and capillary samples from the same patients for is fully not understood.

Table 33. Lymphocytes, Chempaq XBC. Evaluation 2
Analytical imprecision (CV_{within}) and Bias, venous and capillary samples.

	Coulter			Chempaq						
GP	N	Mean (range)	CV_{within} (95CI%)	Sample	N	Bias	95 % CI	N	CV_{within}	95% CI
	LY x 10 ^{9}/L		% %	LY x10^9/L		%	%		%%	%
A	39#	1,95(1,0 – 3,65)	*3,1 (2,5 – 4,1)*	Capillary	39	**-7,2**	-10,2 – -4,1	39	9,2	7,4 – 12,2
				Venous	32	**-10,1**	-13 – -7,0	32	6,0	4,8 – 7,9
B	42	1,86(0,6 – 3,0)	*2,6 (2,2 – 3,3)*	Capillary	41	**7,6**	1,4 – 13,8	40	9,4	7,8 – 12,1
	Coulter			Chempaq						
	LY %			LY %						
A	39#	31,4(10 – 45)	*3,0 (2,4 – 3,9)*	Capillary	40	**-8,2**	-11,1 – -5,2	39	6,7	5,5 – 8,6
				Venous	32	**-9,9**	-13,1 – -6,7	32	6,7	4,4 – 8,9
B	42	27,5(9 – 45)	*2,7 (2,3 – 3,5)*	Capillary	40	**3,1**	-0,9 – 7,1	40	7,2	5,9 – 9,2

one sample excluded. * outlier according to Burnett. The results in bold fulfils the quality goals. GP A had a high percentage of errors in the beginning and was asked also to measure venous samples.

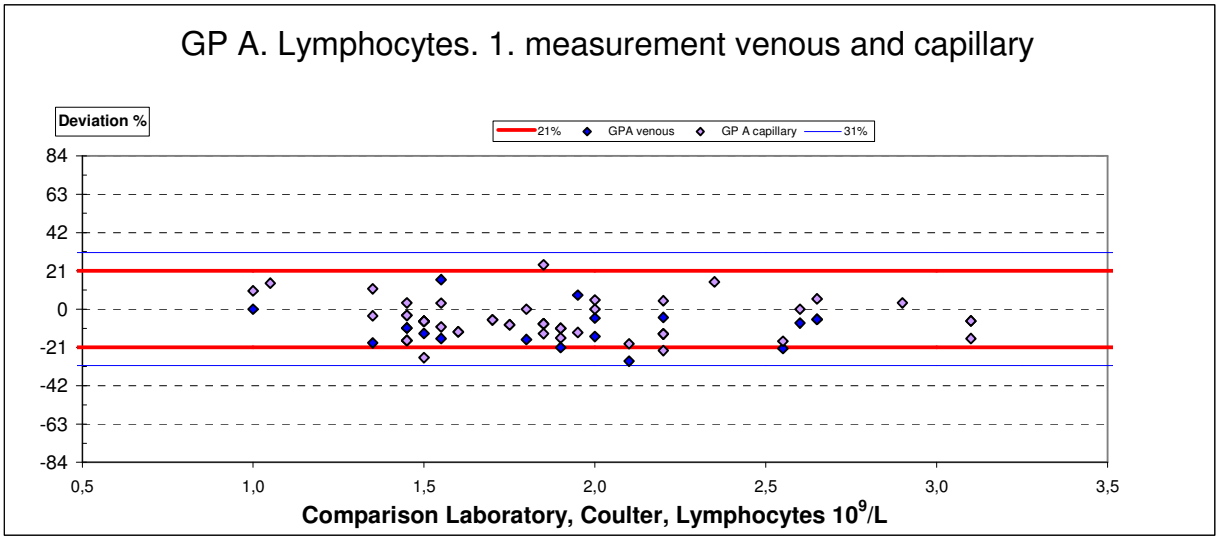
Figure 29. Lymphocytes x 10^9/L. Total Error. Hospital outpatients.



The diagram shows the deviations of the Chempaq XBC results with capillary and venous samples. X-axis = mean of comparison method, duplicate results and Y-axis = ((first Chempaq XBC result– mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. 95 % of the results should be within the acceptance limits. Acceptance limits of SKUP is ± 21 %. (Chempaq expected ± 31%). For concentrations of ≤0,3 x 10^9/L a deviation 100% was accepted.

The figure 29 demonstrate that a Total Error of less than 21% compared to Sysmex SE 9000 is almost achieved for Lymphocytes measured by Chempaq in venous and capillary samples.

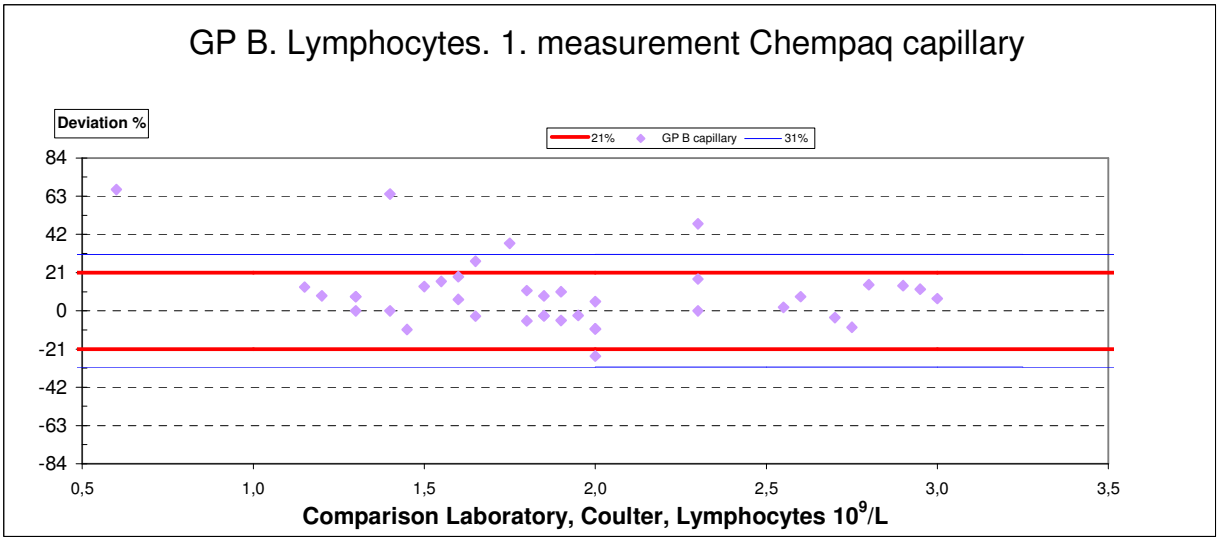
Figure 30. Lymphocytes x 10^9/L. Total Error. Primary Care.



The diagram shows the deviations of the Chempaq XBC results with capillary and venous samples. X-axis = mean of comparison method, duplicate results and Y-axis = ((first Chempaq XBC result– mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. 95 % of the results should be within the acceptance limits. Acceptance limits of SKUP is ± 21 %. (Chempaq expected ± 31%)

Figure 30 demonstrate that a Total Error of less than 21% can be achieved for Lymphocytes in primary health care compared to Coulter results in both contrations and in percentage.

Figure 31. Lymphocytes. Total Error. Primary Care.



The diagram shows the deviations of the Chempaq XBC results with capillary and venous samples in the two General Practitioners laboratory. X-axis = mean of comparison method, duplicate results, and Y-axis = ((first Chempaq XBC result – mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. 95 % of the results should be within the acceptance limits. Acceptance limits of SKUP is ± 21 %. (Chempaq expected ± 31%)

The SKUP goal of a deviation of less than 21% was reach in one of the primary care centres. The expectation from the producer (deviation less than 31%) was not even reached in the other primary care centre (GP B).

Table 34 Total Error. Lymphocytes, Outpatients. Hospital and Primary Care

		Interval LY x 10 ^{9}/L	N	Deviation < ±21% %	Deviation 95% within limits* %
Hospital	Capillary samples	0,5 – 3,59	37	**94,6**	—
	Venous samples		37	92	**22**
GP A	Capillary samples	1,0 – 3,65	39	**95**	—
	Venous samples		32	92,5	**23**
GP B	Capillary samples	0,6 – 3,0	41	85,4	48
		Interval LY %			
Hospital	Capillary samples	15 – 41	37	88,8	25
	Venous samples		37	58	33
GP A	Capillary samples	10 – 45	40	**94,7**	—
	Venous samples		32	**96,8**	—
GP B	Capillary samples	9 – 45	39	**97,5**	—

*percentage limits for 95% of results. The results in bold fulfils the quality goals. The interval belongs to the comparison method.

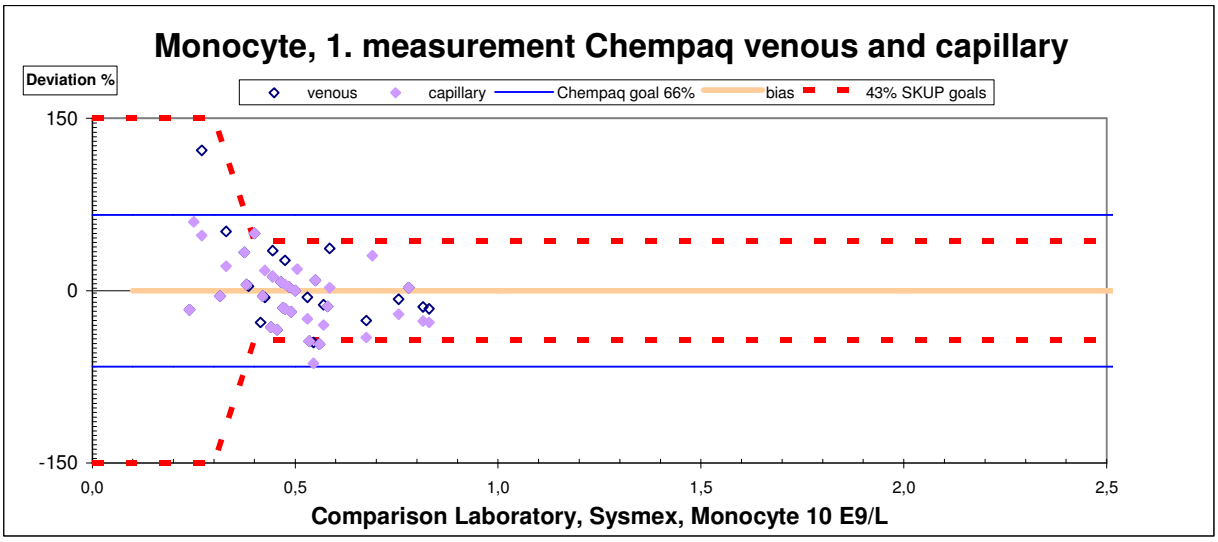
For one of the primary care centres and in hospital a deviation of less than 21% was achieved for both venous and capillary samples. For the other centre not even the expectations from the producer with a deviation less than 31% were fulfilled.

Table 35 Monocytes, Chempaq XBC. Evaluation 2
Analytical imprecision (CV_{within}) and Bias, venous and capillary samples, concentration and %.

	Coulter			Chempaq						
GP	N	Mean (range)	CV_{within} (95CI%)	Sample	N	Bias	95 % CI	N	CV_{within}	95% CI
	MO x 10 ^{9}/L		% %	MO x 10^9/L		%	%		%	%
A	39#	0,47 (0,2 – 0,8)	*7,8 (6,3 – 10,4)*	Capillary	39	27,9	15 – 40	39	12,9	10,4 – 17,1
				Venous	31	30,0	14 – 46	31*	**7,8**	6,3 – 10,4
B	42	0,51 (0,2 – 0,85)	*7,9 (6,5 – 10,1)*	Capillary	41	39,5	25 – 54	40	**9,4**	7,8 – 12,1
	Coulter			Chempaq						
	MO %			MO %						
A	39#	7,5 (4,0 – 11,7)	*8,8 (7,3 – 11,4)*	Capillary	39	26,4	14 – 39	39	**8,9**	7,3 – 11,5
				Venous	32	30,6	17 – 44	32	**8,9**	7,2 – 11,8
B	42	7,6 (3,7 – 14,1)	*7,6 (6,3 – 9,7)*	Capillary	40	33,6	21 – 46	40	**6,7**	5,5 – 8,6

one sample excluded. * outlier according to Burnett. The results in bold fulfils the quality goals. GP A had a high percentage of errors in the beginning and was asked also to measure venous samples.

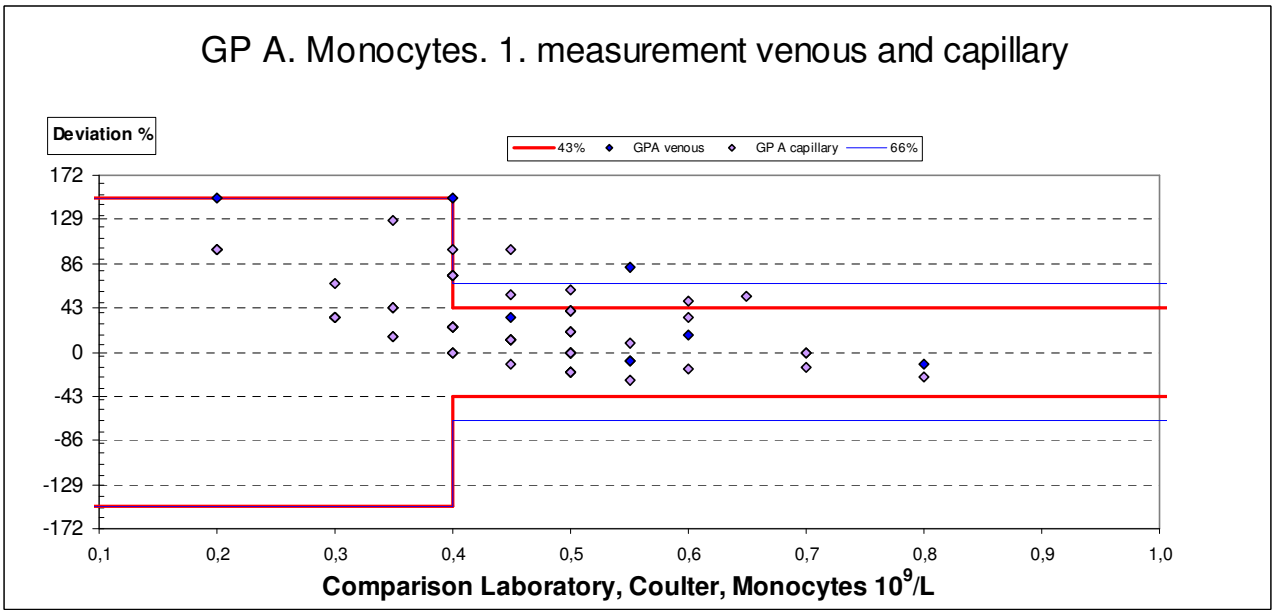
Figure 32. Monocytes. Total Error. Outpatients hospital.



The diagram shows the deviations of the Chempaq XBC results with capillary and venous samples. X-axis = mean of comparison method, duplicate results and Y-axis = ((first Chempaq XBC result– mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. 95 % of the results should be within the acceptance limits. Acceptance limits of SKUP is ± 43 %. (Chempaq expected ± 66%). For concentrations of ≤0,4 x 10^9/L a deviation 150% was accepted.

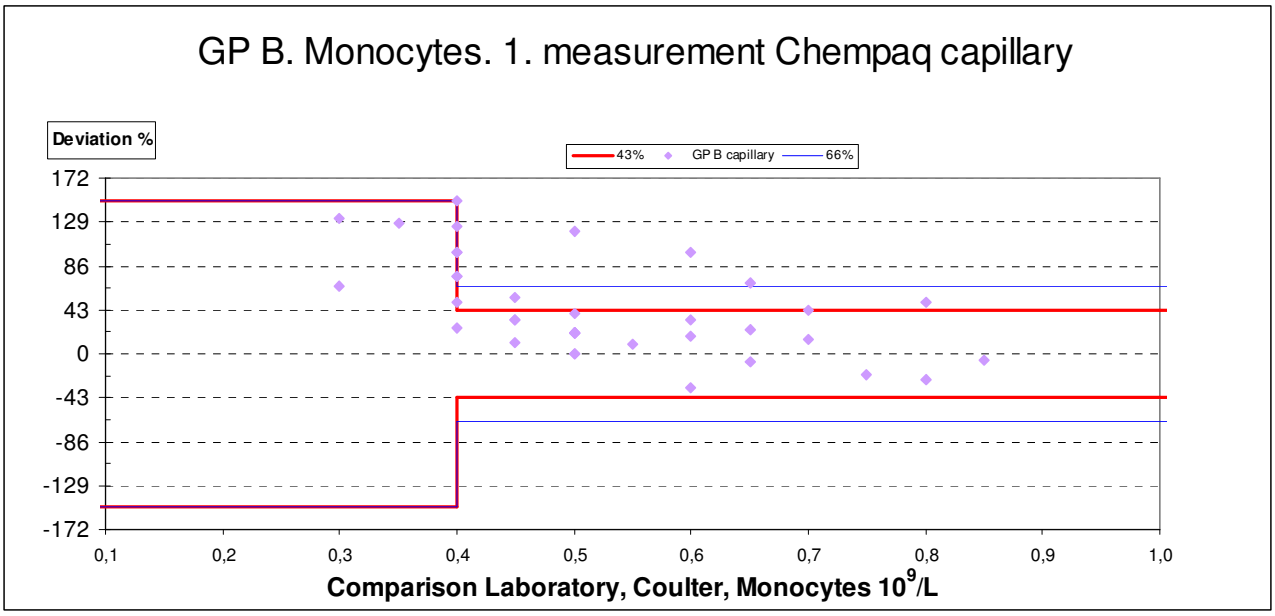
Total Error was less than 43% for outpatients in hospital.

Figure 33. Monocytes. Total Error. Primary Care.



The diagram shows the deviations of the Chempaq XBC results with capillary and venous samples. X-axis = mean of comparison method, duplicate results and Y-axis = ((first Chempaq XBC result– mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. 95 % of the results should be within the acceptance limits. Acceptance limits of SKUP is ± 43 %. (Chempaq expected ± 66%) For concentrations of ≤0,4 x 10^9/L a deviation 150% was accepted.

Figure 34. Monocytes. Total Error. Primary Care.



The diagram shows the deviations of the Chempaq XBC results with capillary and venous samples. X-axis = mean of comparison method, duplicate results and Y-axis = ((first Chempaq XBC result– mean of comparison method, duplicate results)/mean of comparison method, duplicate results) x 100. 95 % of the results should be within the acceptance limits. Acceptance limits of SKUP is ± 43 %. (Chempaq expected ± 66%). For concentrations of ≤3,0 x 10^9/L a deviation 100% was accepted.

Figure 30-34 demonstrates that Coulter and Chempaq do not measure the same cells in the concentrations belowe 6 to 7.0 x 10^9/L. The same pattern was seen in the hospital testing with Sysmex SE 9000 in fig 23 and 32. However in hospital against sysmex the deviation was less.

Table 36 Total Error. Monocytes. Outpatients. Hospital and Primary Care

		Interval MO x 10^9/L	N	Deviation < ±43% %	Deviation 95% within limits* %
Hospital	Capillary samples	0,2 – 0,9	36	**95#**	—
	Venous samples		36	**97,3**	—
GP A	Capillary samples	0,2 – 0,8	38	78	100
	Venous samples		30	94	100
GP B	Capillary samples	0,2 – 0,85	40	81	100
		MO %			
GP A	Capillary samples	4,0 – 11,7	40	71,1	95
	Venous samples		32	74,2	150
GP B	Capillary samples	3,7 – 14,1	39	66,6	100

The results in bold fulfils the quality goals. *95% of the results are within this deviation. The interval is for the comparison method. # about 95%

Validation analytical quality, hospital and primary care evaluation 1 and 2

Bias. For granulocytes, lymphocytes and monocytes SKUP have the goals less than 9,1%, 12% and 26% and the Chempaq expectations were 7%, 9% and 20% respectively. The goals/demands are for both concentrations and percentages (from fraction of one) of differentials.

The error due to reagent leakage during primary care evaluation 1 did also affect the bias and total error of the three part differential.

In Primary care evaluation 2 the SKUP goals of bias was fulfilled for Granulocytes and Lymphocytes, but not for monocytes, where the bias was +26% to +39% in average. This was due to a very high bias for the low values. The range for Monocytes were in primary care 0,2 to 0,8 x 10^9/L. Measuring 0,3 in Chempaq and 0,2 x 10^9/L in the comparison method give a bias of 50%. Chempaq measure consequently a little more monocytes than Sysmex SE 9000/Coulter in both severely ill hospitalised patients as well as outpatients.

Imprecision: The imprecision in the three part differential is independent from the results of Leukocyte count. However, when the technical error was discovered in the cassettes used for the first evaluation, it was not certain, that the imprecision could not be improved with correct cassettes).

Granulocytes
The goal of SKUP was less than 8,1 % and Chempaq expected less than 7%.
CV_{within} in venous samples was 4,3 and 4,9%, which is less than the imprecision in Chempaq of 5,8% in the hospital laboratory. The explanation might be that it is 'healthy' outpatients, while the majority in the hospital were chosen due to their abnormal values. In the outpatients in the hospital the imprecision was 3,3% (2,7-4,4%)

In primary care evaluation 1, the imprecision of the capillary samples was 6,6 and 8,5%; in both centres it was below 8,1% in the last 20 samples. In the second evaluation in primary care the imprecision in the venous samples was still fulfilling the goals while the capillary samples had an imprecision of 8,7 and 9,8%.

The goal for the granulocytes was fulfilled for the percentages (from fraction of one) of differentials.

Lymphocytes
The goal of SKUP was less than 5,2 % and Chempaq expected less than 13%.
In primary care evaluation 1 CV_{within} in venous samples was 7,7 and 6,2%, which is corresponding to the imprecision of 6,3% for the outpatients in the hospital.
In primary care the imprecision of the capillary samples was between 7,0 and 9,4. The goal of SKUP was not achieved for venous nor capillary samples. The goal of Chempaq was fulfilled for both venous and capillary samples.

Monocytes
The goal of SKUP was less than 10 % and Chempaq expected less than 28%.
In the primary care CV_{within} in venous samples was 10 % or less below while the capillary samples had a CV-within of 13-14% in the first evaluation and 8.9 to 12.9% in the last evaluation.
In hospital the corresponding imprecision was 8.0 and 9.3% in venous and capillary samples for outpatients.

Total Error
Granulocytes
The goal of SKUP was that at least 95% of the results should deviate less than ±23 % from the comparison method. Chempaq expected the deviation to be less than 19%.
Concentration: The goal of SKUP was fulfilled for the capillary samples from hospital but not for the corresponding venous samples, where only 89% was within ±23%. The reason was the bias for leukocyte concentration. Venous and capillary samples > 3,0 x 109/L in primary care fulfilled the goals.

Lymphocytes
The goal of SKUP was that at least 95% of the results should deviate less than ±21 % from the comparison method. Chempaq expected the deviation to be less than 31%.
Concentration: The goal of SKUP was fulfilled for the capillary samples from hospital and GP A, but not for GP B that had only 85% within ±21%. For the venous samples 95% was within ±23% in hospital and GP A.

Monocytes
The goal of SKUP was that at least 95% of the results should deviate less than ±43 % from the comparison method. Chempaq expected the deviation to be less than 66%.
Concentration: The goal of SKUP was fulfilled for the samples from hospital, but not for primary health care evaluation. 62 to 80 % in GP A and GP B was within ±43%. The reason for this was the low concentrations of monocytes (less than $0.5x10^9$/L).

Conclusion Three part differential (Granulocytes, Monocytes, Lymphocytes)

The Three part differential results from the hospital laboratory performed by an experienced laboratory technologist and the two primary care centres showed that the goals of SKUP were not fulfilled for all the components in both hospital and primary care.

For the granulocytes the goals were fullfilled in one primary care centre and from the hospital evaluation (only for capillary samples).

For the lymphocytes the goal of SKUP was almost fulfilled for the hospital and GP A, but not for GP B that had 10% of measurements deviating even more than the expectation of the producer.

For monocytes the goal of SKUP was fulfilled for the samples from hospital. In the primary health care centres only between 62 and 80 % of the results were within ±43%. The reason for this is probably that Chempaq XBC measures the number of monocytes a little higher than Sysmex SE 9000 and Coulter (~$0.2x10^9$/L) does.

Special groups of patients:
Flags: Severely ill patients: The laboratory had more remarks in the differentials than Chempaq, however, there were good agreement in duplicates in 'flags'.

Eosinophilocytes were counted as granulocytes. Thus, Chempaq XBC cannot be used to detect patients with a increased number of eosinophilocytes.

Chempaq cannot be used for detection of patients with mononucleosis infectiosa

Less than 1% of results from outpatients in primary care had flags in Chempaq XBC.

5.9. Quality Controls

5.9.1. *External Quality Controls Chempaq*

Table 37. Coulter high, low and normal, Hospital

		Mean	CV total	CV within	CV between
Control-low, n=21					
LKC	10^9/L	1,8	10,6	4,4	9,7
LY	10^9/L	0,8	20,4	12,5	16,2
MO	10^9/L	0,3	8,7	0,0	8,7
GR	10^9/L	0,7	21,4	13,8	16,3
Haemoglobin	mmol/L	4,2	3,4	1,8	2,9
Control-normal, n=22					
LKC	10^9/L	5,0	3,6	3,1	1,9
LY	10^9/L	2,0	21,2	16,3	13,6
MO	10^9/L	0,7	7,4	6,0	4,3
GR	10^9/L	2,3	16,4	9,8	13,2
Haemoglobin	mmol/L	8,2	2,7	1,2	2,4
Control-high, n=23					
LKC	10^9/L	12,5	2,2	1,9	1,2
LY	10^9/L	4,7	16,3	10,4	12,6
MO	10^9/L	1,7	3,1	3,1	0,5
GR	10^9/L	6,1	11,7	6,5	9,7
Haemoglobin	mmol/L	11,4	2,3	1,6	1,6

5.9.2. *Quality Controls. Human,*

('living control'. two capillary specimens from one healthy individual were drawn 20 times over a period of two months)

Table 38. Chempaq

date	lot no.	WBC	LY	MO	GR	Hb	%LY	%MO	%GR
25-04-2005	108	6,9	2,1	0,5	4,4	8,4	29,8	7,6	62,6
	108	6,3	1,9	0,4	4,0	8,3	30,2	6,8	63,0
27-04-2005	109	7,6	2,2	0,6	4,8	9,1	29,5	7,9	62,5
	109	7,0	2,1	0,5	4,4	8,8	29,4	7,7	62,9
28-04-2005	109	6,5	2,0	0,5	3,9	8,6	31,6	7,7	60,8
	109	5,6	2,0	0,5	3,1	8,0	35,9	8,2	56,0
29-04-2005	109	5,2	1,7	0,4	3,1	8,7	32,5	8,1	59,4
	109	5,0	1,4	0,4	3,1	8,4	28,8	8,1	63,1
02-05-2005	109	5,7	1,9	0,5	3,4	8,5	33,5	7,9	58,5
	109	5,6	1,8	0,4	3,4	8,3	32,6	7,6	59,8
03-05-2005	108	6,6	1,7	0,4	4,5	8,2	25,3	6,5	68,1
	108	6,9	1,6	0,4	4,9	8,4	23,4	5,9	70,6
04-05-2005	108	6,2	1,7	0,4	4,1	8,5	26,6	7,0	66,4
	108	6,3	1,7	0,4	4,1	8,4	27,6	6,9	65,6
09-05-2005	110	5,8	1,9	0,5	3,4	9,2	33,2	8,2	58,6
	110	4,9	1,7	0,4	2,8	8,4	35,4	7,8	56,8
10-05-2005	110	4,6	1,8	0,4	2,5	9,2	38,4	8,7	52,9
	110	4,5	1,8	0,4	2,3	9,1	40,2	9,3	50,5
11-05-2005	110	5,4	1,7	0,4	3,3	8,9	31,1	7,6	61,3
	110	4,7	1,5	0,4	2,8	8,7	32,5	8,2	59,3
12-05-2005	109	4,9	1,5	0,4	3,0	9,1	30,2	7,8	62,0
	109	4,7	1,2	0,3	3,2	9,0	26,2	6,9	67,0
17-05-2005	108	4,7	1,8	0,4	2,6	8,6	37,1	8,8	54,0
	108	4,6	1,7	0,4	2,6	8,4	36,1	8,3	55,6
18-05-2005	110	5,2	1,9	0,5	2,9	9,3	36,3	8,8	54,9
	110	5,0	1,9	0,4	2,7	9,2	37,2	8,7	54,1
19-05-2005	110	4,9	1,7	0,4	2,9	9,0	33,8	8,0	58,2
	110	4,8	1,8	0,4	2,6	8,9	36,9	8,4	54,7
20-05-2005	108	4,4	1,5	0,3	2,6	9,0	33,4	7,6	59,0
	108	3,8	1,3	0,3	2,2	8,9	34,6	7,7	57,7
23-05-2005	108	4,6	1,6	0,4	2,6	8,9	35,6	7,6	56,8
	108	4,5	1,5	0,4	2,6	8,6	33,8	8,0	58,1
30-05-2005	110	5,5	1,6	0,4	3,4	9,1	29,9	7,3	62,7
	110	5,3	1,6	0,4	3,4	9,1	29,5	7,0	63,5
31-05-2005	109	5,4	1,8	0,4	3,3	9,2	32,3	7,6	60,1
	109	4,1	1,3	0,3	2,5	8,6	31,9	7,6	60,5
02-06-2005	112a	5,8	1,5	0,4	3,8	8,4	26,3	7,5	66,2
	112a	6,2	1,6	0,5	4,1	8,6	26,3	7,6	66,1
13-06-2005	112a	5,1	1,5	0,4	3,2	8,7	29,7	7,2	63,1
	112a	6,0	1,7	0,4	3,8	9,2	28,2	7,4	64,5
Mean		5,4	1,7	0,4	3,3	8,7	31,8	7,7	60,4
Standard deviation		0,879	0,224	0,062	0,713	0,343	3,957	0,670	4,537
CV% total		16,2	13,1	15,0	21,6	3,9	12,4	8,7	7,5
CV% biological (between)		14,7	10,7	10,6	20,1	2,9	11,8	7,8	7,1
CV% Analytical		7,2	7,8	10,8	8,5	2,7	4,6	4,0	2,7

CV% Analytical: impression from capillary sampling is included in the results.

5.9.3. *Stability of control material*

Figure 35a and 35b Stability of material from Coulter and pool from laboratory (LKC)

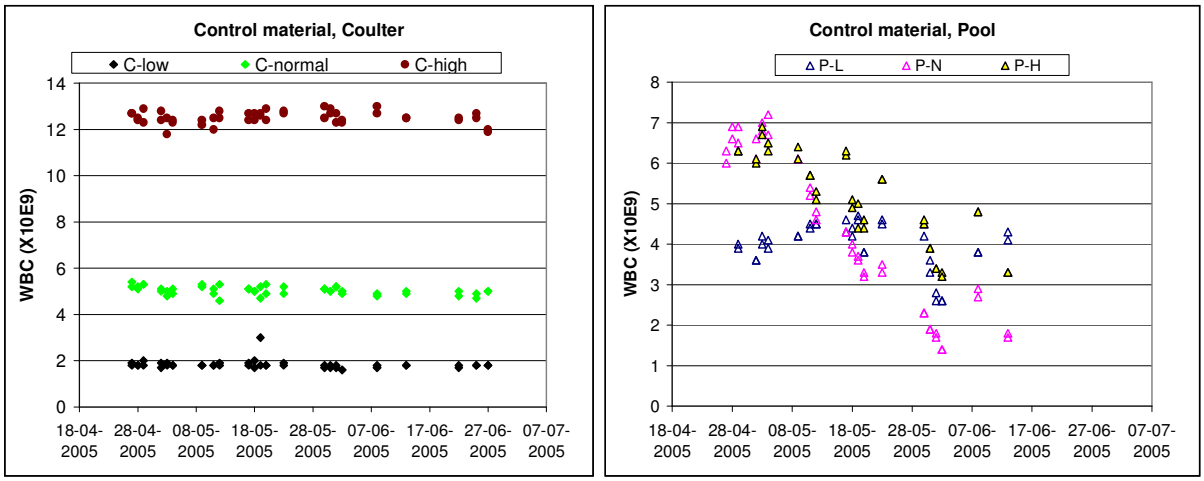
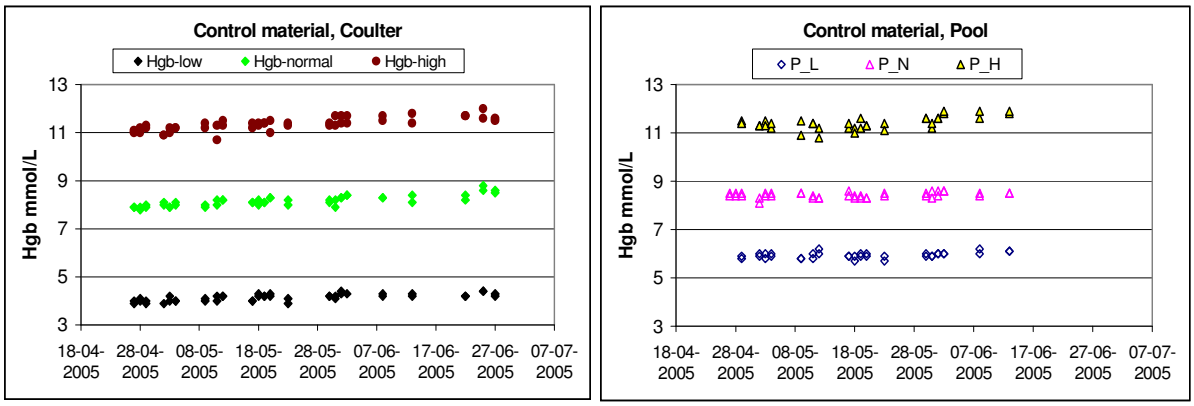


Figure 35c and 35d Stability of control material (Haemoglobin)



The control samples is analysed by 5 different lot numbers.

5.9.4. *External Quality Controls Chempaq*

Table 39. Coulter high, low and normal in primary health care.

		GP A		GP B	
		Mean	CV total %	Mean	CV total %
Control-low		n=8		n=11*	
LKC	10^9/L	1,6	*4,5*	1,7	*5,8*
LY	10^9/L	0,4	*35,9*	0,6	*28,6*
MO	10^9/L	0,2	*16,6*	0,3	*17,1*
GR	10^9/L	1,1	*11,2*	0,9	*17,1*
Haemoglobin	mmol/L	4,3	*2,4*	4,4	*4,6*
Control-normal		n=8		N=26**	
LKC	10^9/L	4,9	*2,9*	5,1	*3,7*
LY	10^9/L	0,7	*56,8*	1,2	*41,6*
MO	10^9/L	0,6	*15,4*	0,7	*20,0*
GR	10^9/L	3,7	*10,7*	3,3	*14,7*
Haemoglobin	mmol/L	8,3	*3,0*	8,5	*2,7*
Control-high		n=7		N=23***	
LKC	10^9/L	12,3	*3,1*	12,6	*5,5*

LY	10^9/L	1,8	*59,7*	3,1	*55,9*
MO	10^9/L	1,5	*14,0*	1,5	*19,8*
GR	10^9/L	8,9	*10,9*	7,9	*20,5*
Haemoglobin	mmol/L	11,6	*1,6*	11,8	*2,6*

* one outlier, ** 2 outliers, *** 3 outliers according to Burnett. In case of outliers in one result, the whole measurement is excluded.

External Quality Controls

In table 39 and table 41 it is shown that the Coulter high and normal, but not low control, are in the area in which Chempaq have goals for the analytical quality. In figure 35 the controls are visualised. 5 lots were used for the controls. Haemoglobin and Leukocytes are within CV ± 3 and 5% for the imprecision for Control-normal and Control-high, while the CV% as expected was higher for the very low control with Hgb 4,2 mmol/L CV = 3,4% (recommended < 3,0%) The Leukocytes mean was 1,8 x 10^9/L, and the CV% (10,6%) was expected to be less than 5% for values higher than 3,0 x 10^9/L.

Due to the stability, storage conditions and waste percent of the controls it is not likely that the general practitioners will chose them as a part of their control system. Haemoglobin and Leukocytes can be used by organisations for external quality control. The control samples can not be used for three part differentials.

Validation:

The imprecision of the Haemoglobin controls were from 1.6 to 4.6% in the range of 4.3 mmol/L to 11.8 mmol/L. This is a little higher than the imprecision of the genuine samples and a little higher than in hospital laboratory.

The imprecision of the Leukocytes controls did fulfil the goals of less than 5,5% in all levels.

In the beginning of the evaluation SKUP was given Coulter controls with lower values than expected. Therefore 3 genuine pools were made and measured in duplicates every day during the testing. (6 extra samples) The CV-total for Hb was 1,7%, 1,4% and 2,1%, mean values 5,9 mmol/L, 8,4 mmol/L and 11,4 mmol/L respectively.

5.10. Interference

- Leukaemia cells se Haemoglobin, figure 4, 5 and 9. No interference.
- Viscosity/ M-components (IGM). No interference.
- Haematocrit. No interference. Data not shown.

The sample is diluted 400 times in the PAQ. If the viscosity in the sample is very high, the flow in the PAQ is too slow, and errors occur.
The errors did not appear in the samples with Leukocytes $\leq 100 \times 10^9$. One patient with 325×10^9 Leukocytes /L gave Error 96 twice, the error code is 'sample out of range'. A patient with Sysmex SE 9000 Leukocytes 98×10^9 gave the answer '$> 100 \times 10^9$' twice. 20 other patients with counts between 20 and 100×10^9 Leukocytes /L had no errors. The M-components (IgM) did not interfere with the analysis for the few patients having IgM.
Haematocrit was measured in duplicates in all samples and gave no interference with haemoglobin or Leukocytes. Data not shown.

5.11. Errors

General practitioners in Denmark do not accept more than 2% waste due to errors in test strips or cassettes. For the patient samples this goal was achieved.
The error frequency in the control material was expected to be higher than 2% despite mechanical turning of the sample in the laboratory.
Evaluation 1 In total there were 29 errors at Chempaq in 750 analyses. 11 were from patient samples, one duplicate 'error 96' which means 'sample out of range' was due to Leukocytes = 325×10^9 /L. Eight samples showed 'error 60' and one 'error 49'. These errors are all indicating that flow through the cassette is too slow. The percent of errors in the patient sample was 1,8 (9 of about 500).
The error frequency in the control material was higher: 18 of approximately 250 ~ 7,2%. 10 showed 'error 60', six had 'error 54' and 1 'error 49 and 57'. These errors are all indicating that flow through the cassette is too slow.
Evaluation 2 In both primary care centres there were a total of 14-15% of cassettes with errors. Mainly 'error 60'. The lot used (131) were examined at Chempaq, that found a technical error in the production. (see enclosure). The errors were inhomogeneous. In some packages with cassettes, there were no errors, and in others there were more than 50%.

5.12. Evaluation of user friendliness

The ratings of the staff that performed the evaluation are marked with coloured fields. At the evaluations in the general practices, only the white fields are filled in. At the evaluation in the hospital laboratory, the blue fields are also filled in. Any free comments belonging to the four sub-areas will be placed under the table concerning the area.
An average rating is made for each of the four sub-areas: Insert, Time factors, Quality Control and Operation. The summary of the user friendliness is based on the rating of all sub-areas. 2 or 3 points fulfil the expectations, 0 or 1 point does not fulfil the expectations. If 0 or 1 point is given the reason is explained in the text.

Table 40 User friendliness estimated in the hospital laboratory

Information in the manual / insert about:	0 point	1 point	2 point	3 point
Content, clearness in presentation	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Specimen collection	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Materials required, provided/not provided	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Pre-analytic/test procedure	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Interpretation of the results	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Measurement principle	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Error sources	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Troubleshooting	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Insert available in Danish, Norwegian, Swedish	No	Partly. DK+UK+S ¤	Yes	English + Scandinavian
Easy to read?	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Rating of the manual / insert			Satisfactory	

¤ Orion Diagnostica Sweden has received kit inserts in Swedish. Orion Diagnostica Norway has decided to use kit insert in Danish.

Table 41

Time factors	0 point	1 point	2 point	3 point
Pre-analytic time	>10 min	6 to 10 min.	3 to 5 min.	≤ 2 min.
Analytic time	>20 min	10 to 20 min.	5 to 10 min.	≤ 5 min.
Training / Education	Very difficult	Difficult	Easy	Very easy
Stability of test, unopened, (no/package)	≤ 3 months	3 — 5 months	6 — 12 months	> 12 months
Stability of control material *	≤ 3 months	3 — 5 months	6 — 12 months	> 12 months
Storage conditions of tests, unopened	-20^{0}C	2 — 8 ^{0}C	15 — 30^{0}C	2 — 30^{0}C
Storage conditions of control material	-20^{0}C	2 — 8 ^{0}C	15 — 30^{0}C	2 — 30^{0}C
Rating of time factors				

the control material was 'specially' imported from Ramcon. We used it during 2 months; stability (1½ to 3 month) is varying from lot to lot. Chempaq provides a control material from January 2006, which is stable for 150 days. This material is not part of this testing

Table 42

Quality Control	0 point	1 point	2 point	3 point
Internal quality control, capillary	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
External quality control	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Interpretation of the Quality Control **	Unsatisfactory	Less satisfactory	Satisfactory C-normal, C-high	Very satisfactory
Rating of quality control				

Human control. ** For Leukocytes and Haemoglobin.

Table 43

Operation	0 point	1 point	2 point	3 point
To prepare the test / instrument	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
To prepare the sample	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Application of sample	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Amount of sample	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Procedure step	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Interpretation of the test	Very difficult	Difficult	Easy	Very easy
Sources of errors	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Cleaning/maintenance	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Hygiene, using the test	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Environmental requirements	Poison	Special arrangement	Biohazard	Daily renovation
Demands to education	Lab technician	Course	GP personal	None
Demands to training	days	> 2 hours	½-2 hours	0-30 minutes
Size and weight of package	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Rating of operation			Satisfactory	

Comments:

- The results were printed out. The paper was glued to ordinary paper with different brands of glue. Glue of the brand TESA® made the numbers on the paper disappear after weeks. The experiment was repeated, and the numbers were gone after 14 days.
- In the evaluation we used a Control Material from Coulter. The material is made special by Beckman Coulter in USA at request. The storage stability of this material is varying from batch to batch and so do the target values. In our material the low Control were under the desired limit and cannot be expected to meet the criteria for CV. As Quality Control this can not be recommended for primary care. See 2.2.3. It can be used for troubleshooting by consultants for general practitioners.

Table 44. User friendliness estimated in the General Practice

	0 point	1 point	2 point	3 point
Rating of the manual / insert	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Rating of time factors	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Rating of quality control	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory
Rating of operation ¤	Unsatisfactory	Less satisfactory	Satisfactory	Very satisfactory

An average rating is made for each of the four sub-areas: Insert, Time factors, Quality Control and Operation. The summary of the user friendliness is based on the rating of all sub-areas. The ratings

of the staff that performed the evaluation was 'satisfactory' or 'very satisfactory' except: 'application of the sample', which was 'less satisfactory' in both primary care centres.

Comments: B: One has to be very careful with the application of the drop of blood when measuring 'capillary' samples
A: difficult to 'hit' the right place when placing the drop of blood – better marking of the hole
A: When errors, it takes a long time to get the answer

Conclusion: B: Very easy to use. Very easy to read the result
A: more interesting, if we had the CRP result included in the measurement.

Summary of the user friendliness

The ratings of the Information in Manual / Insert, Quality Control, Time factors and Operation were 'satisfactory' for both venous and capillary samples in Hospital and primary care. Both primary care centres found the instrument very easy to use. The results were easy to read. Both centres also pointed out that the application of the samples, especially the capillary ones could be difficult.
Some brands of glue make the prints to disappear after 14 days.

6. Total Error, Imprecision and bias

1. Total Error

95 % of the tests should deviate < 5 % for **Haemoglobin**: The venous samples fulfil the requirement. 95% of the capillary samples have a Total Error of ± 5,7; 8% and10% in Hospital, Primary care A and Primary care B.

Total Error < 16% is fulfilled for the venous samples for **Leukocytes** > 3,0 x 10^9/L when adjusted for bias. In hospital and primary care A the capillary samples also deviated less than 16% from Sysmex SE 9000 in the interval 3 to 25 x 10^9/L. In Primary care B only 83% were within the limit.
Granulocytes ***Concentration****:* The goal of ±23% was fulfilled for the capillary samples from hospital but not for the corresponding venous samples, where only 89% was within ±23%. Venous and capillary samples > 3,0 x 10^9/L in primary care fulfilled the goals. **%:** The SKUP goal for the granulocytes was fulfilled for the percentages (from fraction of one) for all samples in hospital and primary care.
Lymphocytes ***Concentration****:* The goal of ±21 % was fulfilled for the capillary samples from hospital and GP A, but not for GP B that had only 85% within ±21%. For the venous samples 95% was within ±23% in hospital and GP A. **%** The goal was fulfilled for all samples in primary care in evaluation 2. For the capillary samples in hospital 95% was within a deviation of 25% while the venous samples were within 33%. Goal of Chempaq: 31%.
Monocytes ***Concentration***: The goal of ±43 % was fulfilled for about 90% of the samples from hospital. 62 to 80 % in GP A and GP B was within ±43%. The reason for this was the deviation for the low concentrations of monocytes (less than 0.5x10^9/L). **%:** The goal for the monocytes was not fulfilled. The reason was the low concentrations of monocytes (<6% or 7.0%). 95% of the samples in hospital 95% was within a deviation of 66%, which was the goal of Chempaq.

2. CV_A (imprecision)

CV_A < 3% **Haemoglobin** fulfil the requirement.

CV_A < 5,5% **Leukocytes** was fulfilled for all venous samples – also the ones with flags, which should be repeated or manually counted. It was also fulfilled for capillary samples in hospital, bur not for capillary samples in primary care (5,8-8,3% in four evaluations).

CV_A % for the **Granulocyte**s without flags was less than 8,1% for the venous samples. The capillary samples were fulfilling the goal in hospital and in two of the four evaluations in primary care.

CV_A % for the **Lymphocytes** without flags was higher than ±5,2% in hospital and primary care for all samples. The goal of Chempaq - less than 13% - was fulfilled for all samples.

CV_A % for the **Monocytes** without flags was less than 10% for most samples in hospital and primary care highest CV was 13,7 % and less than the goal of Chempaq (28%).

3. Bias
Calculations made by the mean value of duplicates.

Bias < 2% For **Haemoglobin** was fulfilled in hospital and but not quiet in primary care: 2%; 2,1% and 2,6%.

Bias (< 6,6%) **Leukocytes** was fulfilled for venous samples in total – the high values in hospital had a bias ~ 7,5% after adjusting for bias in the comparison method. In evaluation 2 in primary care bias was < 6,6% for all samples

Bias for the **Granulocyte**s without flags was less than 9,1% for all samples in evaluation 2.

Bias for the **Lymphocytes** without flags was less than 12% in hospital and primary care for all samples.

Bias for the **Monocytes** without flags was higher than 26% for primary care in evaluation 2 (from 26 to 39%)

4. Invalid tests: < 2 %.
   Was fulfilled in the first evaluation, In the second evaluation the percent of errors was 14-15% in both primary health centres.

User friendliness

- The ratings of the Information in Manual / Insert, Time factors and Operation were 'satisfactory'.
- Both centres pointed out that the application of the samples, especially the capillary ones could be difficult
- In some prints numbers disappeared after 2 weeks if a certain glue used, (TESA ®).

7. Conclusion

The evaluation was done with capillary and venous samples from 40 random outpatients, venous samples from 59 selected outpatients and 43 selected patients in hospital under standardised conditions in the hospital laboratory. In addition Chempaq XBC was evaluated in two primary care centres in Denmark. Each of them included 40 individuals (40 capillary and 40 venous samples in duplicate). The two primary health care centres had to repeat the testing for the capillary samples due to a technical problem with the cassettes used.

Haemoglobin: The results achieved at the hospital laboratory and in primary care did fulfil the quality goals for bias, imprecision and total error in venous and samples.
In capillary samples the goals for total error less than 5% was not fulfilled. This was due to a positive bias of 2 – 2.6% (the demands were ≤2%) combined with an imprecision of 3% (the demands were ≤3%) in primary care and -1,7 and 2,33 percent in hospital laboratory. The results are similar to previous SKUP evaluations for measurement of haemoglobin in capillary blood (SKUP/2001/17 and SKUP/2004/29). The reason for the systematic discrepancy between capillary and venous samples is most likely preanalytical.

Leukocytes: The results from the hospital laboratory performed by an experienced laboratory technologist did fulfil the quality goals in both venous and capillary samples for imprecision and total error.
The Bias of 10-14% in the first primary care evaluation was reduced to 0-4.5% in the second evaluation. The goals for capillary samples were fulfilled in one of the two primary health care centres. Only 83% of the capillary samples were within ±16% of the comparison method in the other centre. This was due to a positive bias of about 4.5% combined with an imprecision of 7.6%. In both primary health care centres the imprecision was significantly better in venous samples than in capillary samples, this may be attributed to capillary sampling

The Three part differential results from the hospital laboratory performed by an experienced laboratory technologist and the two primary care centres showed that the goals of SKUP were not fulfilled for all the components in both hospital and primary care.

For the ***granulocytes*** the goals were fulfilled in one primary care centre and from the hospital evaluation (only for capillary samples).

For the ***lymphocytes*** the goal of SKUP was almost fulfilled for the hospital and GP A, but not for GP B that had 10% of measurements deviating even more than the goals of Chempaq.

For ***monocytes*** the goal of SKUP was fulfilled for the samples from hospital. Only between 62 to 80 % in primary care was within ±43%. The reason for this is probably that Chempaq measure the concentrations of monocytes a little higher than Sysmex SE 9000 and Coulter (~0.2x10^9/L).

Eosinophilocytes were counted as granulocytes.
Chempaq cannot be used for detection of allergic patients with a high number of eosinophilocytes.

Variant Lymphocytes: Chempaq cannot be used for detection of patients with mononucleosis infectiosa

Flags:
Chempaq had less than 1% of flags in outpatients. In the severely ill patients the laboratory had more remarks in the differentials than Chempaq. In 36 of 142 selected samples the Sysmex system

indicated in duplicates the need for a manual differential counting. In 18 of them Chempaq also had flags in duplicates, in 2 Chempaq had flags in one of the duplicates while 16 had no remarks in Chempaq. Of these 16 9 were normal or had band neutrocytes, 2 had variant lymphocytes. In total 7 selected 'in hospital' patients had early stages of granulocytes in Sysmex in low concentrations without flags in Chempaq.

Errors
Less than 2% of the samples in evaluation 1 had to be repeated due to errors. 14% had errors in evaluation 2.

The user friendliness of the 'Manual', 'Time factors' and 'Operation' were 'satisfactory' in the hospital laboratory. Both primary care centres pointed out that the application of the samples; especially the capillary ones could be difficult. A part from this both centres found the user friendliness 'satisfactory' or 'very satisfactory'. The imprecision seemed to improve in the last 20 samples compared to the first 20 samples for both haemoglobin and Leukocytes. This was the case for venous samples as well as for capillary samples. A certain brand of glue used (tesa lim-stift, Beirsdorf, Spain) made the prints vanish after 14 days.

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Enclosure A

Comments to Quality Issues revealed at the SKUP study of Chempaq XBC
28. February 2006 - FAP

Increased Haemoglobin Measurements
During "SKUP Praksisafprøvningen" it was revealed that the haemoglobin results were biased up to +10%, which should be compared to the approximately +2%, which was found during the "SKUP Laboratory Study".

The problem was investigated and it could be concluded[1] that the faulty high haemoglobin results were caused by a vaporization of diluent with caused the haemoglobin results to drift outside the specifications and such giving too high results. It was also concluded that the shelf-life should be restricted to three months at maximum 25°C.

Corrective Action
Appropriate action was taken towards the customers (e.g. removing PAQ cassettes older than three months from the market).

Preventive Action
Short term
The expiration date was reduced to three months at 25°C after manufacturing; already produced PAQ cassettes were relabelled in order to reflect the three months shelf-life. The labelling on future produced PAQ cassettes was updated to include a three months shelf-life.
Long term
Activities have been initiated to improve the stability of the PAQ cassettes in order to ensure a shelf-life of 6 months or longer (Quality Issue 1043(2) 06-01).

Comments: The latest produced LOT WIS 001 (Jan '06) is biased relatively 0.0 mmol/L compared to the ICSH reference method. The small bias can also be confirmed by the latest DEKS testing (an independent proficiency testing program) where the Chempaq XBC results (on LOT WIR 131) had a bias on +0.15 mmol/L compared to the mean value (results attached).

Elevated Frequency of Error Codes
Test and use of the last produced PAQ cassettes have identified a too high frequency of Error Codes. The level can in worst case be up to 14% (the average is significant lower), which shall be compared to the approximately 2% seen during the "SKUP Laboratory Study".
The problem was investigated and it could be concluded that the cause of the elevated frequency of Error Codes is due to the fact that lubrication process was out of control (specifications).

Corrective Action
Customers have received appropriate information regarding the quality issue.

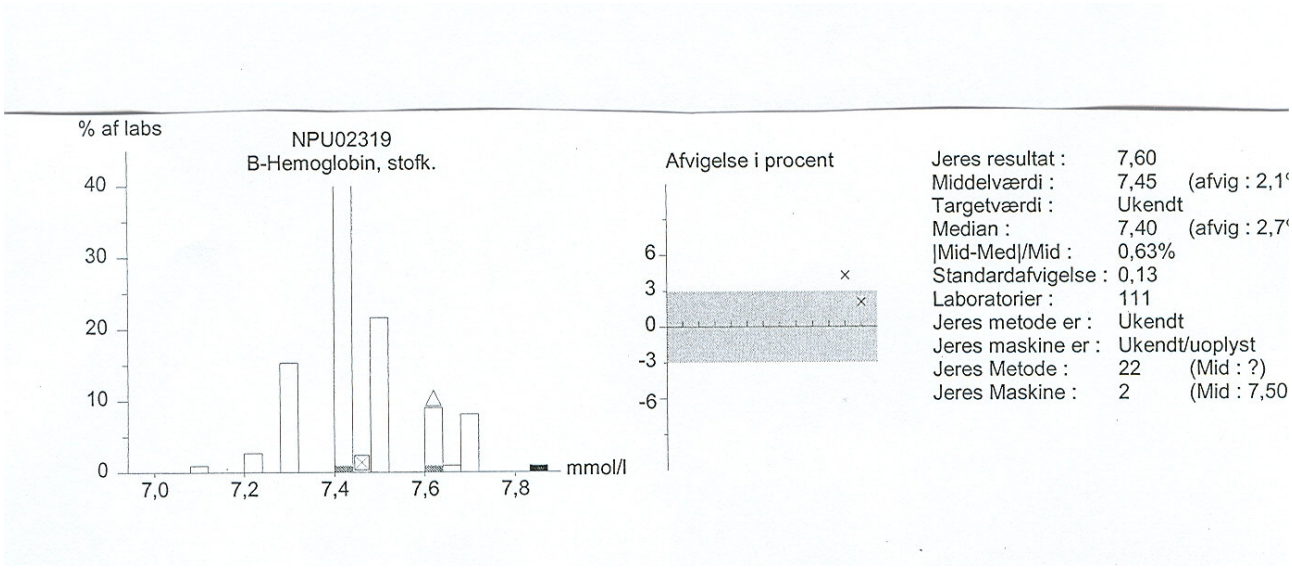
Preventive Action
The lubrication process has been brought back in control (inside specifications) which ensures a level of Error Codes at approximately 2%. A number of Error Codes are caused by clots in the blood samples.

Comments: The latest produced LOT PAQ cassettes WIS 003 (March '06) has an ok level of Error Codes on 2.8%.

Chempaq considers the above issues to be handled in a correct and sufficient manner.

[1] By determine the amount of diluent it could be concluded that approximately 10% of the diluent was vaporised from the PAQ cassettes.

Results from DEKS



Enclosure B

Vigtig information
vedr. PAQ, WIS 001

Farum, 7. februar 2006

Vi har gennem vores løbende kvalitetstest af producerede PAQ konstateret en forhøjet fejlfrekvens, ca. 4-5 % over vores acceptable niveau, på PAQ fra batch WIS 001. Det er fejlkoderne 49-63, som vi forventer, vil forekomme i større udstrækning end normalt. Det er vigtigt at understrege, at PAQ fra batch WIS 001 fuldt ud lever op til vores strenge krav til analysekvalitet, og alene opstår pga. tilstopning. **Fejlkoderne ved tilstopning har derfor ingen betydning for målekvaliteten.**

Vi beklager meget, at vi på nuværende tidspunkt ikke er i stand til at levere PAQ med en tilfredsstillende kvalitet, samt det besvær det kan give klinikken og jeres patienter.
Så snart vi modtager nye producerede PAQ, vil I få mulighed for at ombytte den rest-mængde, I eventuelt skulle have tilbage af WIS 001. Det er selvfølgelig også muligt at returnere denne sending PAQ med det samme og først modtage PAQ, når den nye batch er klar om ca. 1-2 måneder.

Vi kompenserer naturligvis for alle fejl, som I oplever med WIS 001. I vores bestræbelser på at forbedre kvaliteten, vil vi efterfølgende kontakte jer og aftale et tidspunkt for besøg. Her vil vi aflæse Chempaq XBC instrumentet som led i vores tiltag til kvalitets-forbedring.

For at hæve kvaliteten har vi samtidig besluttet at nedsætte vores PAQ holdbarhed ved stuetemperatur til 3 måneder. Vi tilstræber at komme med en længere holdbarhed, når vores kvalitetsforbedringer er gennemført og eftervist.

Vi står naturligvis til rådighed med yderligere oplysninger vedrørende kvalitet, og beder jer kontakte kvalitetschef Frank Petersen på telefon 44 39 05 19, hvis I har spørgsmål.

Venlig hilsen
Chempaq A/S

Jakob Møller Jensen
Global Sales & Marketing Director

Enclosure C

Analyseforskrift 2000-10-03
Afdeling KKA Side 62 af 92
Odense Universitetshospital Udgave nr. 1

Redigering af leuty

WBC + leuty Parameter/alarm	Alarm - grænser - rules	Hvad gøres
NEUT %	> 85% og LEFT SHIFT og WBC > $20,0x10^9/l$	Manuel leuty
LYMF, antal	ATY/ABN LYMF og lymf >4,0 x $10^9/l$	Manuel leuty
MONO %	>30%	Manuel leuty
EOS %	>45%	Manuel leuty
BASO %	>6%	Manuel leuty
WBC Abn Scg	Bedøm scattergram	Bedøm om WBC kurven er OK

WBC + leuty suspect flags:	Alarm-grænser - rules Q-flag	Hvad gøres
Blasts ?	100	Manuel leuty
Imm Gran ?	200	Manuel leuty
Left shift ?	200 og NEUT% > 85% og WBC > $20,0x10^9/l$	Manuel leuty
Aty/Abn lymf	150 og LYMF > 4,0 x $10^9/l$	Manuel leuty
AbnLy/Aged sample	100	Prøve d.d. manuel leuty. Prøve ikke d.d. - leuty mislykkes, såfremt der **ikke** er medsendt udstrygningspræparat. Husk tekst! Kassér det automatisk udstrøgne præparat.
NRBC ?	100	Manuel leuty
NRBC/PLT clumps	150	Analysér prøven med diff. Vurder scattergram.

Analyseforskrift
Afdeling KKA
Odense Universitetshospital

2000-10-03
Side 63 af 92
Udgave nr. 1

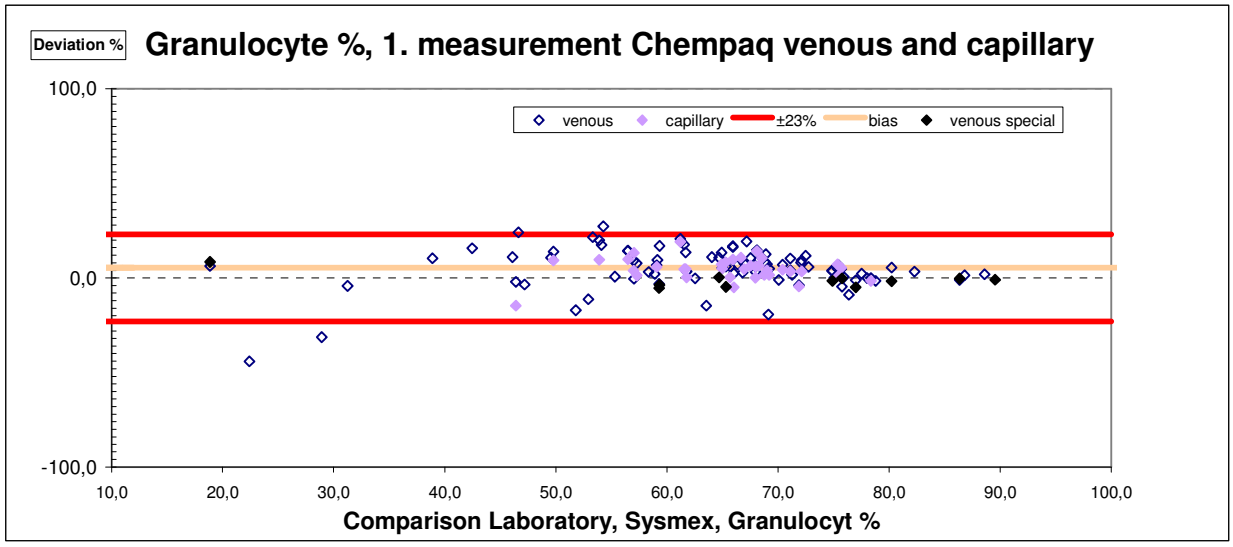
Redigering af Ery.

RBC Parameter/alarm	alarm-grænse	Hvad gøres
MCHC	> 23,2	Genanalyseres ved 37° C.
MCHC	< 18	Kontrollér om prøven evt. er koaguleret.
RBC lyse res.		Fortynd prøven f. eks. 1+3 og genanalysér
FRAGMENTS		KUN SOM KOMMEN-TAR
RBC agglutinerer	100	Genanalyseres ved 37° C.
TURB/HGB interf.	100	Prøven genanalyseres på S/B

PLT parameter/alarm	Alarm-grænse	Hvad gøres
PLT-clumps	150	Analysér prøven med diff. Vurdér scattergram.
PLT > $1500x10^9$/l	$1500x10^9$/l	Fortynd prøven 1+1 med cell-pack, og genanaly-sér.
plt Abn DST		Vurdér PLT-kurve. Den-ne skal starte og slutte "næsten" ved grundlini-en, ellers håndtælles.

Flag	Fulde navn	Betydning	Flag udløst af	Action
WBC/Leu:				Hvis diff bestilt
WBC Abn Scg	WBC Abnormal Scattergram	WBC/Leu unormal scattergram	WBC kurve, Baso diskriminator, ingen diff seperation	Manuel diff
RBC lys res	RBC lyse resistens	RBC/Ery svære at lysere	Diff tælletal > WBC tælletal	Fortyndes 1:2
Blasts?	Blaster	Mistanke om blaster	Celler i blastområdet i IMI kanal	Manuel diff.
Imm Gran?	Immature granulocytter	Umodne grunulocytter/meta, myelo	Celler i imm gran området i IMI kanal	Manuel diff
Left shift?	Left shift	Venstreforskydning/stavkernede	Celler i left shift området i diff eller IMI kanal	Manuel diff.
Aty/Abn Ly?	Atypical/Abnormal lymfocytter	Atypiske/unormale lymfocytter	Celler i atyp lymf området i diff kanal	Manuel diff
AbnLy/Aged?	Abnormal lymfocytter/Aged sample	Lymfoblaster/gammel prøve	Celleantal i diff kanal er < antal i WBC kanal	<24 t man. diff.
NRBC?	Nucleated reed blood cells	Erythroblaster/kærneholdige røde	Celler i NRBC området i diff kanal (ml. ghost og lymf)	Scan for Nrbc
NRBC/PLTCL	Nucleated reed blood cells/platelets clumps	Erythroblaster/thrombocytter klumper	WBC kurven	Scan trc
RBC/Ery:				
RBC Abn Dst	RBC Abnormal Distribution	RBC/Ery unormal fordelingskurve	Erythrocytkurven	Ingen
Dimorph Pop	Dimorphic Populations	To populationer i RBC kurve	To populationer i RBC kurve	Ingen
Aniso	Anisocytose	Anisocytose	RDW-SD > 65 eller RDV-SD > 0,20	Ingen
RBC Agglut?	RBC Agglutination	Mistanke om kuldeagglutininer	MCHC > 24,7, MCH > 2,47, RBC < 3,50	Vandbad
Turb/HGB?	Turbiditri	Mistanke om lipæmi	MCHC > 22,8	Check Plasma
Iron Def?	Iron Defect	Mistanke om jernmangel	MCHC < 18,5 + Hgb < 6,8 + MCV < RDW > 38	Ingen
HGB Defect?	HGB Defect	Mistanke om Hgb unormal	MCV < 75	Ingen
Fragments?	Fragments	Mistanke om Rbc lyseringsrester	Dårlig seperation af Ery og Trc - se kurverne	Ingen
PLT/Trc:				
PLT Abn Dst?	PLT Abnormal Distribution	PLT/Trc unormal fordelingskurve	PFW > 20, øvre diskr. > 30%, nedre diskr. >9%	Scan Trc
PLT Clumps?	PLT Clumps	Mistanke om thrombocyt-klumper	Celler i PLT clumps området i diff/IMI kanal	Scan Trc

Enclosure D
Total Error.
Figure A1 Granulocytes (%). Hospital laboratory.



The diagram is the same as above, just for the percentage of granulocytes

Figure A2 Granulocytes %. Hospital outpatients.

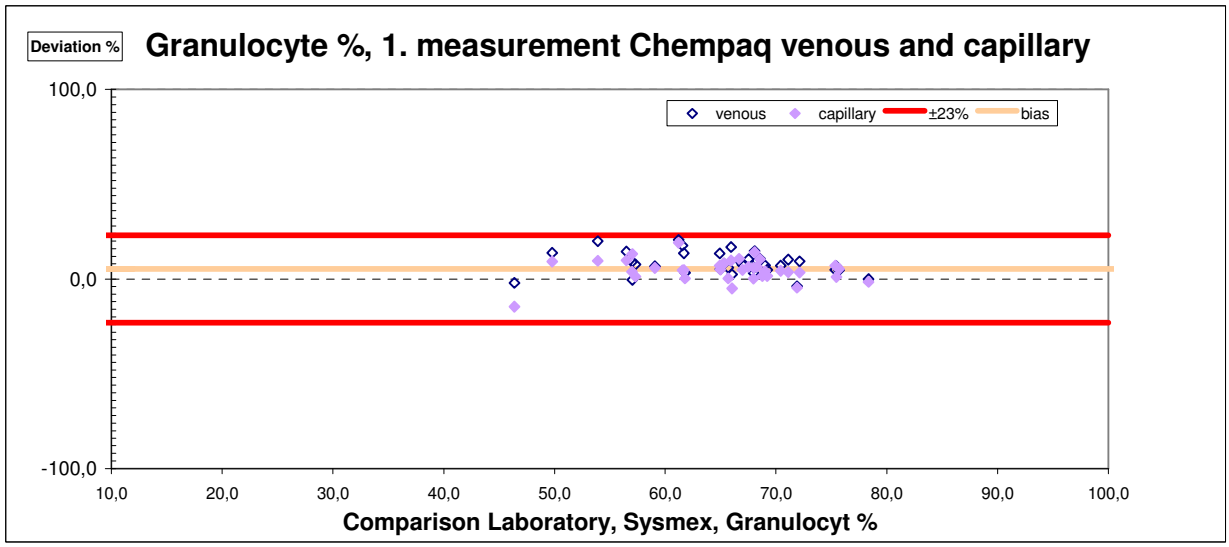


Figure A3 Granulocytes in %. Primary Care.

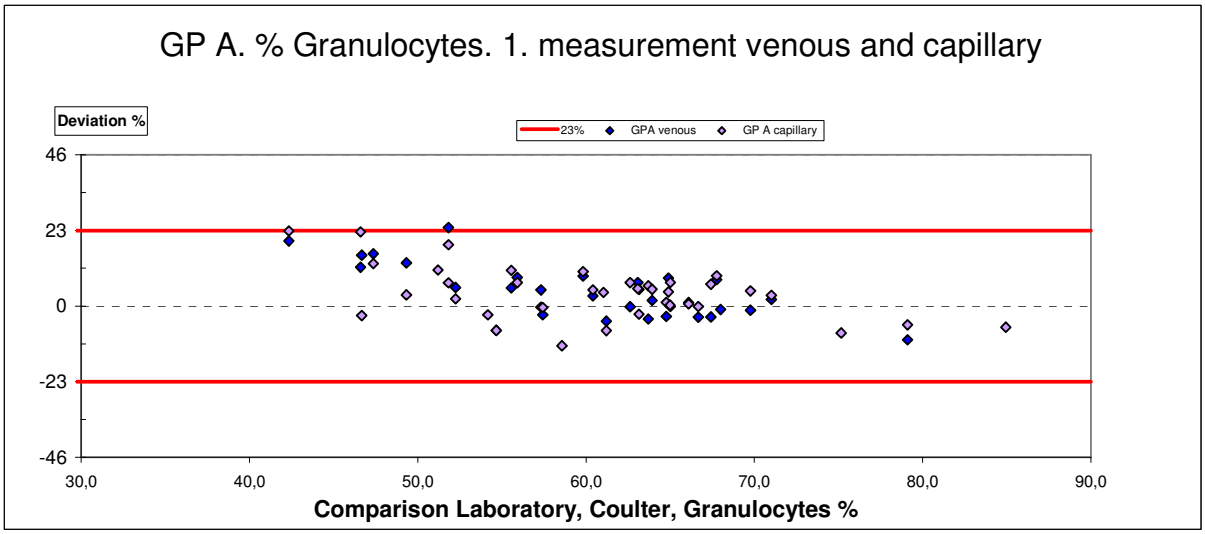
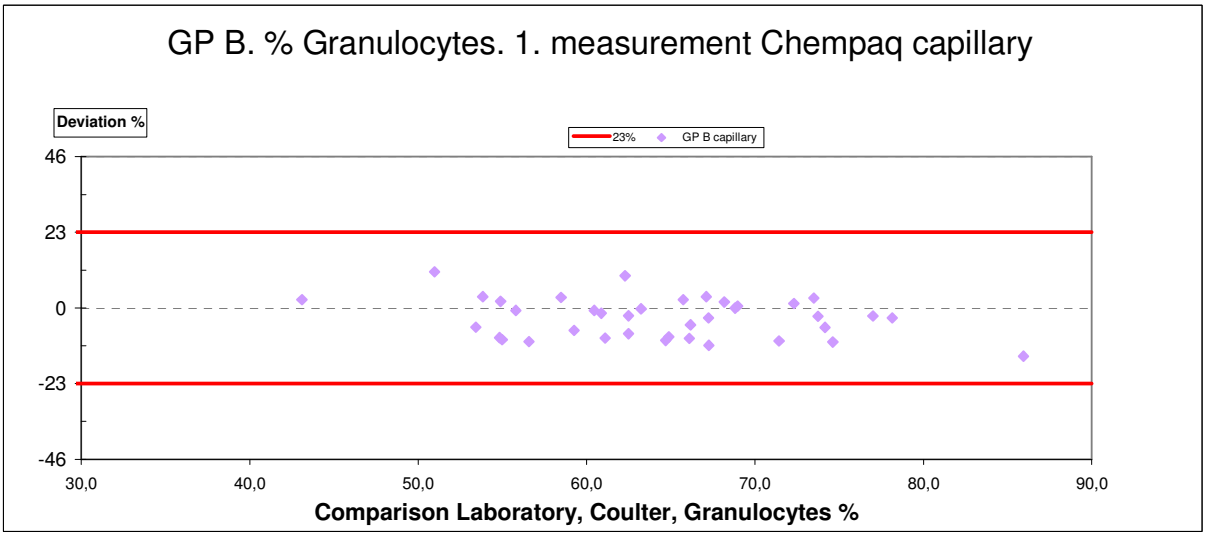


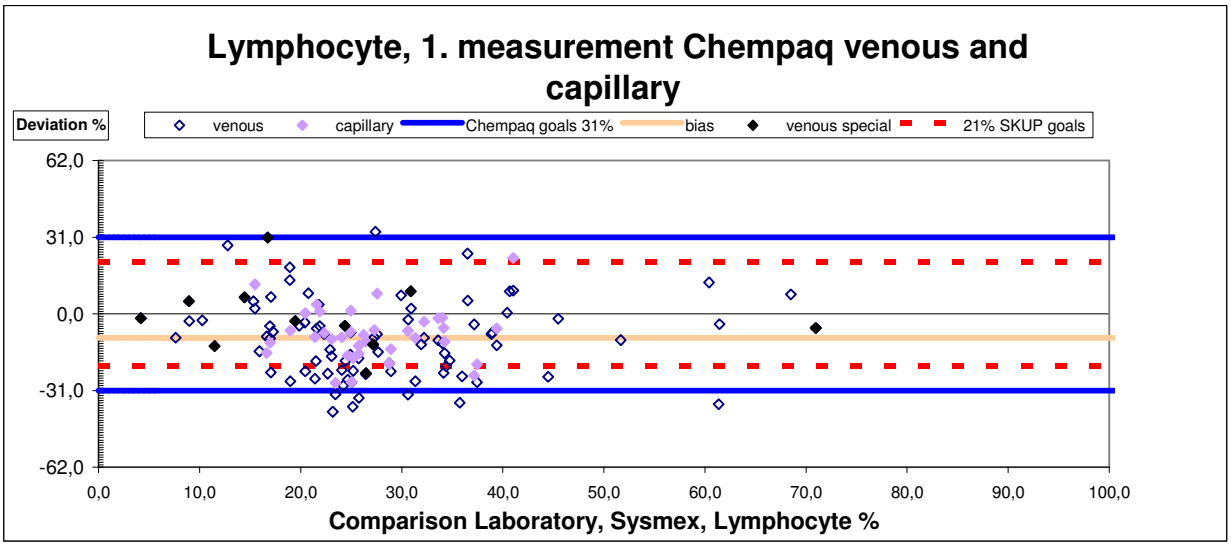
Figure A4 Granulocytes in %. Primary Care.



The diagram is the same as above, just for the percentage of granulocytes

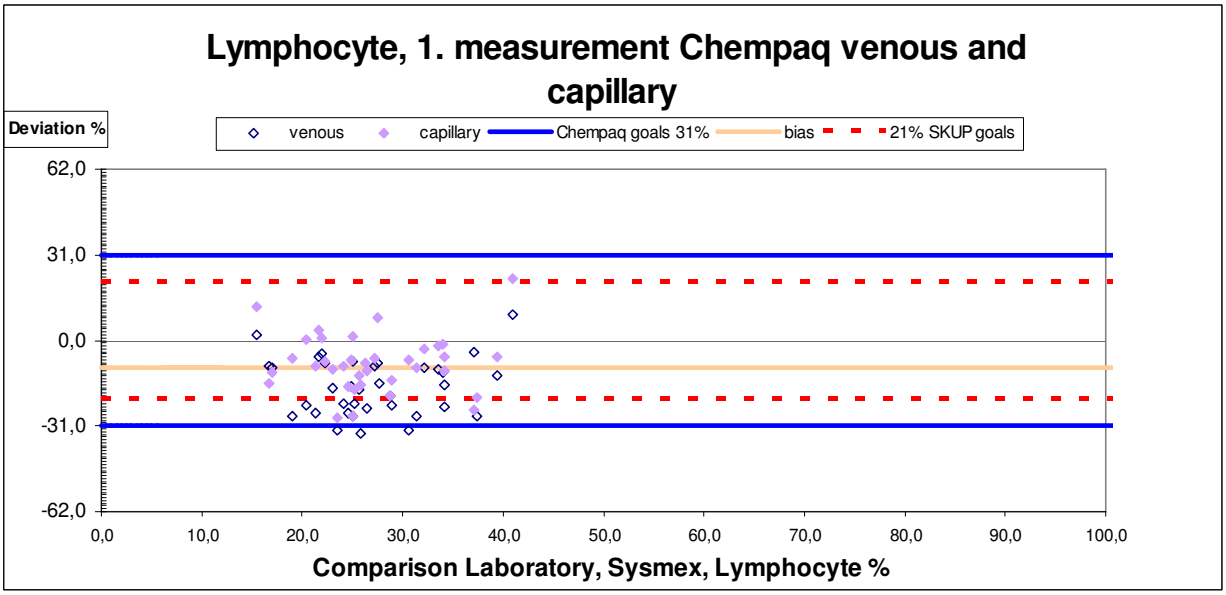
For granulocytes the goal of Chempaq was a deviation less than 19%. This goal was reached for the concentration in hospital and all measurements of granulocytes percentage.

Figure A5 Lymphocytes (%). Hospital laboratory



The diagram is the same as above, just for the percentage of lymphocytes

Figure A6 Lymphocytes %. Hospital outpatients.



The figure demonstrate that Total Error less than 31% was achieved for Lymphocytes in Chempaq compared to Sysmex SE 9000. The goal of less than 21% was not achieved in hospital for 95% of venous sampes. For capillary samples 92,5% fulfilled the goal.

Figure A7 Lymphocytes in %. Primary Care .

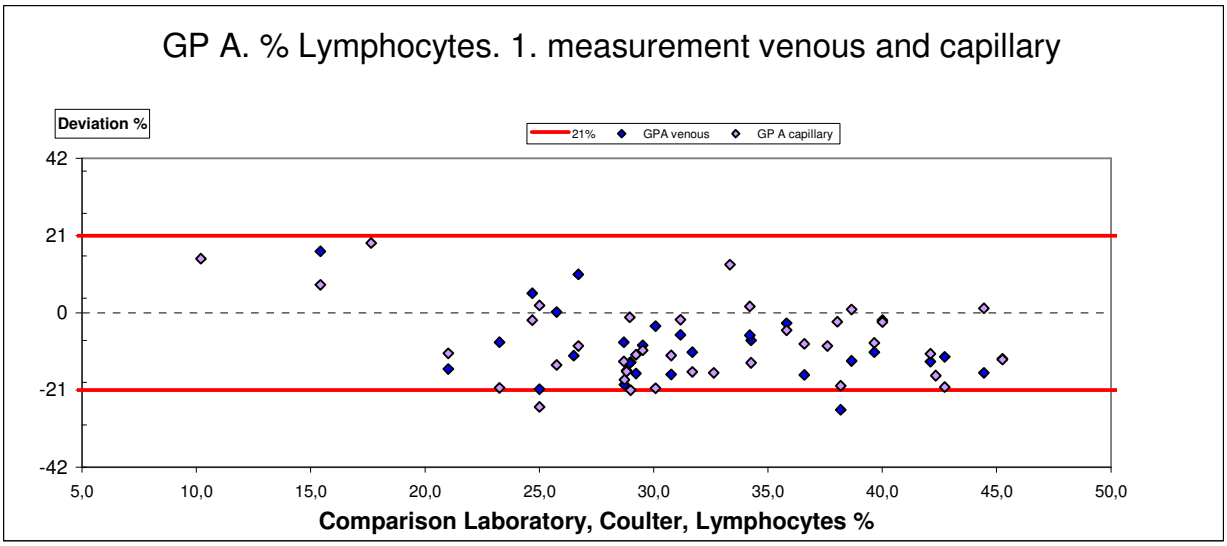
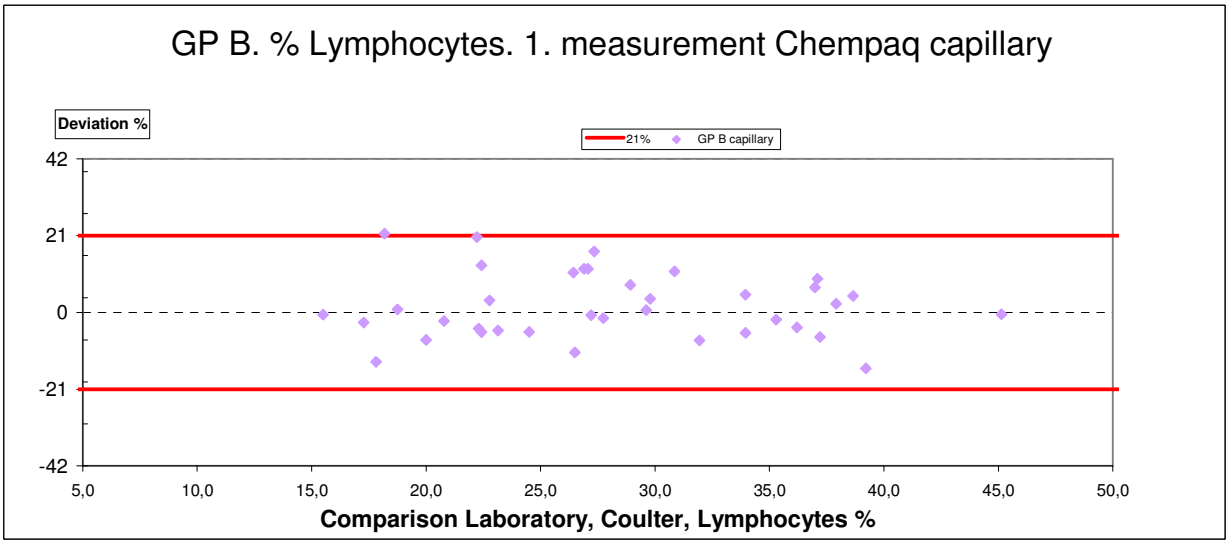


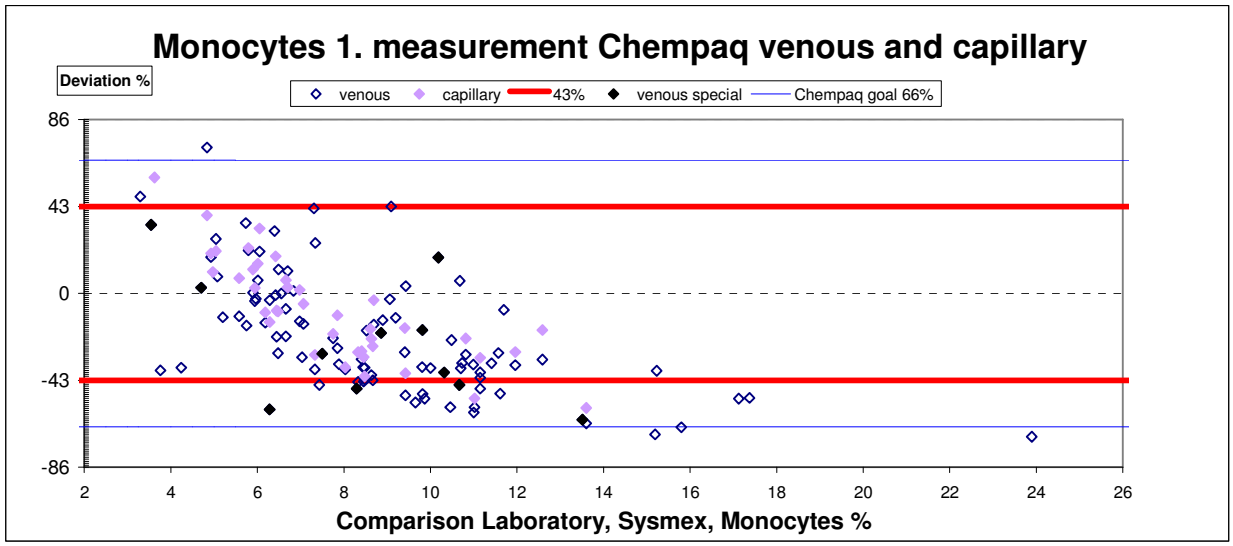
Figure A8 Lymphocytes in %. Primary Care.



The diagram is the same as above, just for the percentage of lymphocytes. One outlier [Coulter 9%, Chempaq 15% not shown ~ deviation +69%]

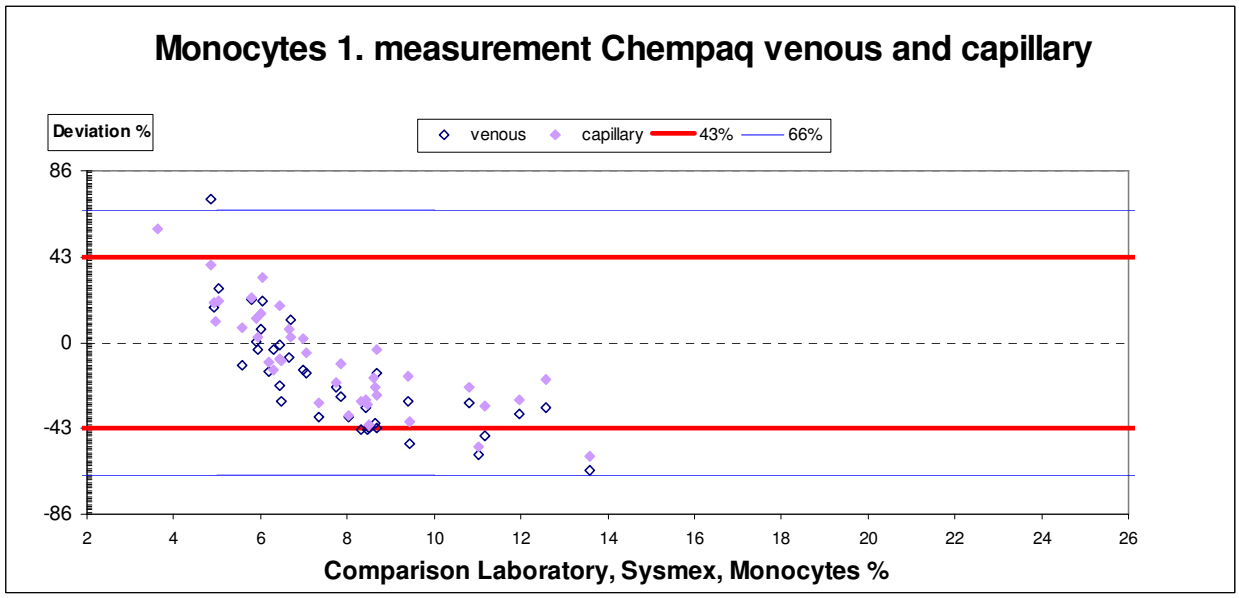
Total Error less than 21% was achieved for Lymphocytes primary care centre A and B for the percentages in both venous and capillary samples.

Figure A9 Monocytes (%). Hospital laboratory



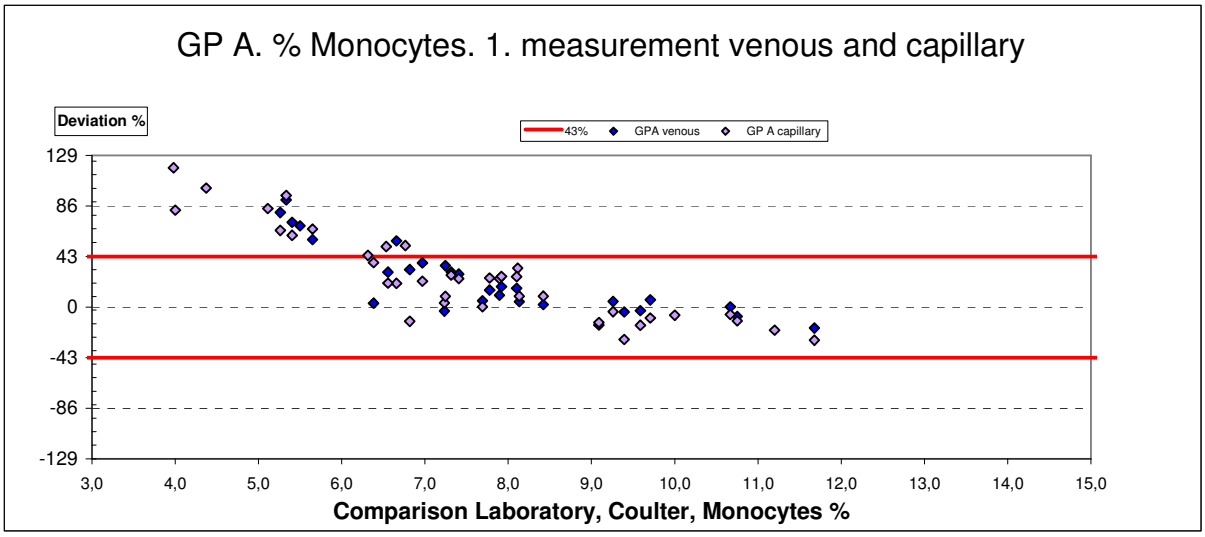
The diagram is the same as above, just for the percentage of monocytes

Figure A10 Monocytes %. Outpatients hospital.



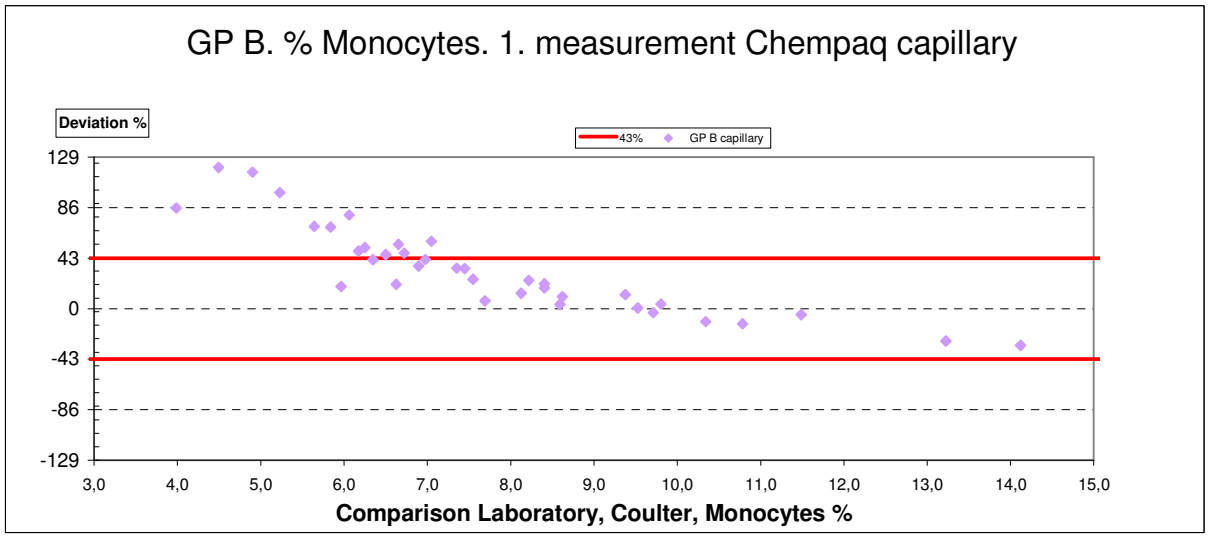
For the percentage Total Error was above 43% for outpatients in hospital.

Figure A11 Monocytes %. Primary Care.



The diagram is the same as above, just for the percentage of monocytes

Figure A12 Monocytes. Primary Care.



The diagram is the same as above, just for the percentage of mon ocytes

Figure A11-A12 demonstrates that Coulter and Chempaq do not measure the same cells as monocytes in the low concentrations/percentages. The same pattern was seen in the hospital testing with Sysmex SE 9000 in fig A9-A10.

Enclosure E

Raw data Evaluation 1

GP A, Venous sample 1 and venous sample 2.

	vene-1	vene-1	vene-1	vene-1	vene-1	vene-1	vene-1	vene-1		vene-2	vene-2	vene-2	vene-2	vene-2	vene-2	vene-2	vene-2
lot	WBC-1	LY-1	MO-1	GR-1	Hb-ven	%LY-1	%MO-1	%GR-1	lot	WBC-2	LY-2	MO-2	GR-2	Hb-ven	%LY-2	%MO-2	%GR-2
112a	5,6	1,4	0,4	3,8	10	24,9	7,3	67,8	112a	5,4	1,4	0,5	3,5	10,1	26	8,6	65,5
112a	6,6	1,7	0,5	4,4	8,8	25,4	7,2	67,4	112a	6,7	1,7	0,6	4,4	9	25	9	66,1
112a	4	1	0,3	2,7	8,9	26,1	7,1	66,8	112a	4,2	1,2	0,3	2,7	9,1	28,1	7	64,9
112a	7,5	1,5	0,5	5,5	8,7	19,7	6,4	74	112a	7,7	1,6	0,6	5,5	8,8	20,8	7,7	71,5
112a	6,8	1,9	0,6	4,3	9,2	28,6	8,4	63	112a	6,9	2	0,6	4,3	9,2	29,4	8,4	62,2
112a	27,3	10,6	3	13,7	10	38,7	11,1	50,2	112a	28,9	9,6	3,2	16,1	10,5	33,1	11	55,9
112a	10,1	2,3	0,8	7	9,2	22,4	8,1	69,5	112a	9,4	2,3	0,8	6,3	8,9	24,5	8,4	67,1
112a	11,9	3,9	1,1	6,9	10,2	32,8	9,6	57,6	112a	12	4	1,2	6,9	10,1	33,1	9,6	57,3
112a	7,3	1,7	0,5	5	9,4	24	7,3	68,8	112a	7,8	1,8	0,6	5,4	9,9	23,3	7,2	69,5
112a	9,5	1	0,6	7,9	8,8	11	6,6	82,4	112a	9,5	0,9	0,6	8	8,7	9,9	6,6	83,6
112a	8,4	2,1	0,6	5,7	9	24,6	7,4	68	112a	8,7	1,8	0,7	6,2	8,9	21,1	7,9	71
112a	9,6	3	0,9	5,7	8,2	31,2	9,2	59,6	112a	9,8	2,8	0,9	6,1	8,4	28,6	9,3	62,1
112a	4,8	0,9	0,3	3,5	8,4	19,6	6,6	73,9	112a	8,3	1,8	0,6	5,9	8,7	21,8	7,5	70,7
112a	8,3	1,9	0,6	5,7	8,5	23,3	7,5	69,2	112a	8,4	1,9	0,7	5,8	8,4	22,8	8	69,3
112a	3,9	0,8	0,3	2,8	7,9	19,5	8,1	72,5	112a	4,2	0,6	0,3	3,3	7,8	15,3	6,2	78,5
112a	10,9	2,6	0,8	7,6	10,1	23,4	7,4	69,2	112a	10,9	2,4	0,8	7,7	10,2	22,3	7	70,7
112a	9,9	2	0,7	7,2	6,2	20	7,1	72,9	112a	9,7	1,8	0,7	7,3	6,1	18,1	7,2	74,8
112a	13,2	1,1	0,8	11,3	10,2	8,3	5,8	85,9	112a	13	1	0,8	11,2	10,7	7,4	5,9	86,7
112a	9,7	1,9	0,7	7,1	8,1	19,5	7,3	73,2	112a	9,4	2	0,6	6,8	8,3	21,2	6,7	72,1
112a	9,7	2	0,9	6,7	10,5	21	9,7	69,3	112a	10	2,1	1	6,8	10,2	21,5	10	68,5
112a	7,1	1,1	0,5	5,6	9,9	15	6,6	78,4	112a	7,2	1,3	0,5	5,5	9,6	17,4	6,6	76
112a	9,9	3,1	0,8	6	8,6	31,2	8,2	60,7	112a	10,2	2,6	0,8	6,7	8,7	26	7,7	66,3
112a	8,2	1,6	0,7	6	8,8	19	8,4	72,6	112a	8,3	1,4	0,6	6,3	8,8	17	7,3	75,7
112a	5,9	2,1	0,6	3,3	8,5	35,7	9,3	55	112a	6,3	2	0,5	3,8	8,7	31,2	8,7	60,1
112a	10,1	1,5	0,6	7,9	8,9	15	6,4	78,6	112a	10,4	1,5	0,5	8,4	9,1	14,2	5	80,8
112a	11	3,3	1	6,8	9,2	29,9	8,7	61,3	112a	11,4	2,9	1	7,5	9,4	25,2	8,7	66,1
112a	9,7	2,3	0,8	6,6	8,2	23,3	8,1	68,6	112a	9,8	2	0,7	7,1	8,3	20,7	7	72,3
112a	7,4	1,9	0,7	4,7	9,5	26,4	10,1	63,5	112a	7,5	2	0,8	4,7	9,6	26,3	10,2	63,6
112a	13,5	2,8	1	9,7	9,8	20,8	7,4	71,8	112a	14,2	2,8	1,1	10,2	9,7	19,9	7,7	72,4
112a	7,6	1,2	0,6	5,8	7,8	15,3	7,7	77	112a	7,3	1	0,4	5,9	7,9	13,9	5	81,1
112a	6,3	1,1	0,5	4,7	9,4	18,2	7,7	74,2	112a	6,3	1,1	0,4	4,8	9,4	17,1	6,7	76,1
112a	4,6	1,3	0,4	2,9	10,7	28,2	9	62,7	112a	4,7	1,4	0,4	2,9	10,4	29,4	8,7	61,9
112a	6,7	2,1	0,6	4	9,6	30,9	8,6	60,5	112a	6,8	1,9	0,6	4,2	9,6	28,8	8,6	62,6
112a	16,5	3	1,5	12	10	18,2	9,1	72,7	112a	15,7	2,9	1	11,8	9,7	18,4	6,1	75,5
112a	6,2	2,5	0,6	3,1	8,3	40,3	9,9	49,8	112a	6,2	2,5	0,6	3,1	8,4	40,1	10,1	49,9
112a	11,3	2,3	0,8	8,2	9,2	20,2	7,1	72,8	112a	10,9	1,8	0,7	8,4	9,4	16,9	6,4	76,7
112a	12,2	1,5	0,7	9,9	7	12,6	6	81,4	112a	10,8	1,3	0,5	9	7	11,8	5	83,2
112a	6,8	1,4	0,5	4,9	9,2	20,6	7,3	72,2	112a	7,1	1,3	0,5	5,3	9,2	18,8	6,9	74,4
112a	8,6	1,9	0,6	6	7	22,2	7,4	70,3	112a	8,7	1,9	0,6	6,2	7,2	21,6	7,2	71,2
112a	11,2	2	0,9	8,4	10,2	17,8	7,6	74,6	112a	10,9	2,2	0,8	7,9	10	19,8	7,6	72,6

The coloured sample had flags in WBC and the differential

GP A, capillary sample 1 and capillary sample 2.

	kap-1	kap-1	kap-1	kap-1	kap-1	kap-1	kap-1	kap-1	lot	kap-2	kap-2	kap-2	kap-2	kap-2	kap-2	kap-2	kap-2
lot	WBC-1	LY-1	MO-1	GR-1	Hb-ven	%LY-1	%MO-1	%GR-1		WBC-2	LY-2	MO-2	GR-2	Hb-ven	%LY-2	%MO-2	%GR-2
112a	5,4	1,6	0,4	3,3	10,3	30,1	8,1	61,8	112a	4,4	1,2	0,4	2,8	9,4	27	8,6	64,4
112a	6,9	2	0,6	4,3	9,1	29,4	8,7	61,9	112a	5,8	1,9	0,5	3,4	8,3	33	8,5	58,6
112a	4,2	1,1	0,4	2,7	9,6	26,6	8,4	65	112a	4,1	1	0,3	2,7	9,2	24,8	8,5	66,7
112a	7,6	2	0,7	5	8,7	26,1	8,8	65,2	112a	6,8	1,7	0,5	4,5	8,2	25,7	7,6	66,7
112a	6,4	2,1	0,6	3,7	8,6	32,6	9,8	57,6	112a	6,7	2	0,6	4,1	8,8	29,8	9,1	61,1
112a	29	10	3,2	15,7	10,1	34,5	11,2	54,3	112a	28,3	7,9	3	17,4	10,2	28	10,6	61,4
112a	9,4	2,5	0,8	6,2	9	26,3	8,2	65,5	112a	9,3	2,3	0,8	6,2	8,6	24,5	8,4	67,1
112a	11,6	3,9	1,1	6,7	9,8	33,3	9,2	57,5	112a	12,8	4,1	1,2	7,5	10,3	32,4	9,1	58,5
112a	7,1	1,9	0,7	4,5	9,6	27,2	9,3	63,5	112a	6,6	1,9	0,5	4,2	9,6	28,3	8,2	63,4
112a	9,4	0,9	0,6	7,8	8,6	9,7	6,5	83,6	112a	8,3	0,8	0,4	7	8,6	10	5	85
112a	8,1	2,1	0,7	5,3	8,8	25,9	8,7	65,4	112a	8,5	1,8	0,6	6,1	8,8	21,1	7,4	71,5
112a	9,4	2,7	0,8	5,9	8	28,9	8,6	62,5	112a	9,3	2,8	0,8	5,7	8,2	30	9	61
112a	8	1,8	0,6	5,6	9	22,4	7,3	70,3	112a	7,8	1,7	0,5	5,6	8,8	21,8	6,3	71,9
112a	8,9	2,4	0,7	5,8	8,2	26,6	7,8	65,6	112a	8,4	2,2	0,6	5,6	8,3	25,7	7,2	67,1
112a	4,2	0,7	0,4	3	7,6	17,6	10,7	71,7	112a	4,1	0,8	0,4	2,9	7,8	19,3	9,7	71
112a	10,2	2,4	0,8	7,1	9,2	23	8	69	112a	11,1	2,3	0,9	7,9	10	20,8	8,5	70,8
112a	11	2,3	0,8	7,9	7	20,9	7,4	71,6	112a	10,7	2,3	0,9	7,6	6,5	21,1	8	70,9
112a	12,4	0,8	1	10,5	11,1	6,8	8	85,2	112a	11,5	0,8	0,7	10,1	10,3	6,5	6	87,4
112a	9,5	2	0,6	7	8	20,8	6,2	73	112a	8,6	1,8	0,6	6,3	7,7	20,7	6,7	72,6
112a	8,4	2,3	0,8	5,3	8,5	27,1	9,4	63,4	112a	9,9	2,5	1	6,4	10,2	25,2	10,1	64,6
112a	6,9	1	0,6	5,2	8,9	15,1	9,4	75,5	112a	7,2	1,1	0,4	5,7	9,7	15	5,9	79,1
112a	9,9	3,3	0,8	5,8	8,8	33,7	7,9	58,4	112a	9,8	2,8	0,8	6,1	9	29,1	7,8	63
112a	7,6	1,8	0,5	5,4	8,5	23,4	6,3	70,3	112a	7,7	1,5	0,6	5,6	8,9	19,8	7,6	72,6
112a	6,3	2,2	0,5	3,5	8,3	35,1	8,6	56,4	112a	6,7	2,1	0,6	3,9	8,7	31,5	9,5	59
112a	10,6	1,8	0,6	8,2	8,9	17	5,8	77,3	112a	8,9	1,6	0,5	6,8	8,2	18,2	5,6	76,2
112a	12,4	3,3	1,2	7,9	9,4	26,9	9,5	63,6	112a	12,2	2,9	1,1	8,2	9,6	24,1	8,6	67,3
112a	9,6	2,4	0,8	6,4	8,5	25,3	8,4	66,3	112a	9,7	2,4	0,7	6,6	8,1	24,7	7,6	67,7
112a	6,9	2,1	0,6	4,1	9,5	31,2	8,6	60,2	112a	6,4	2	0,6	3,8	9,2	31	9,2	59,8
112a	12,5	3,3	1	8,2	9,8	26,3	8	65,7	112a	13,1	3,1	1,1	8,8	9,5	24	8,5	67,4
112a	7,6	1,2	0,4	6	7,8	15,2	5,5	79,3	112a	7,6	1,2	0,4	6	7,7	15,4	5,3	79,3
112a	6,2	1,1	0,4	4,7	8,7	18	6,4	75,5	112a	6,9	1,2	0,4	5,3	9,2	16,7	6	77,3
112a	4,4	1,6	0,4	2,4	8,3	35,4	9	55,6	112a	4,1	1,6	0,4	2,2	10,2	37,6	10,2	52,2
112a	6,6	2,3	0,6	3,8	9,3	34,1	9	56,9	112a	7	2,3	0,6	4,1	9,5	32,9	9	58,1
112a	13,8	2,8	1,1	9,9	8,7	20,1	8	71,9	112a	17,1	2,8	1,5	12,7	9,5	16,5	9	74,4
112a	6,5	2,7	0,7	3,1	8,8	42,4	10,2	47,4	112a	5,9	2,4	0,6	2,9	8,4	41	10	49,1
112a	10,3	2	0,7	7,6	8,9	19,4	7	73,6	112a	10	2,1	0,6	7,3	9,5	21,1	5,7	73,1
112a	11,6	1,5	0,7	9,4	6,7	13,1	5,7	81,1	112a	11,8	1,4	0,5	9,9	7,1	12,2	3,9	83,9
112a	7,7	1,6	0,6	5,5	9,5	21,4	7,5	71,1	112a	7,3	1,6	0,7	5,1	9,7	22,1	9,2	68,7
112a	8,7	2,1	0,7	5,9	7,7	23,9	8,1	68	112a	9,3	2,3	0,7	6,3	7,2	24,7	7,5	67,8
112a	10	2,3	0,9	6,8	9,6	22,7	9,3	68	112a	9,7	2	0,6	7	9,8	21,1	6,5	72,4

The coloured sample had flags in WBC and the differential

Sysmex comparison result 1 and result 2 for GP A

WBC-1	NEU-1	LY-1	MO-1	EO-1	BASO-	Hb-ven	WBC-2	NEU-2	LY-2	MO-2	EO-2	BASO-	Hb-ven
4,71	2,25	1,48	0,53	0,44	0,01	9,4	4,94	2,29	1,64	0,58	0,42	0,01	9,3
5,76	2,86	2,14	0,47	0,28	0,01	8,5	5,48	2,66	2,02	0,49	0,29	0,02	8,5
3,69	1,79	1,22	0,4	0,27	0,01	8,8	3,75	1,9	1,17	0,4	0,26	0,02	8,7
6,56	4	1,9	0,52	0,11	0,03	8,2	6,72	4,15	1,85	0,57	0,13	0,02	8,2
6,21	3,3	2	0,59	0,27	0,05	8,4	6,44	3,54	1,97	0,56	0,27	0,1	8,5
25,31	6,27	14,88	3,99	0,04	0,13	9,8	25				0,05		9,8
8,33	5,5	2,24	0,51	0,08	0	8,5	8,31	5,45	2,31	0,43	0,09	0,03	8,6
10,57	5,29	3,83	0,71	0,72	0,02	9,6	10,55	5,01	3,98	0,81	0,72	0,03	9,6
6,65	4	1,93	0,43	0,25	0,04	9,3	6,64	3,87	2	0,39	0,25	0,13	9,3
8,41	6,42	0,99	0,95	0,03	0,02	8,3	8,54	6,78	0,89	0,84	0,02	0,01	8,4
7,48	4,12	2,17	0,82	0,32	0,05	8,3	7,34	4	2,06	0,91	0,32	0,05	8,3
8,15	4,42	2,6	0,98	0,12	0,03	7,8	7,93	4,28	2,48	1,04	0,1	0,03	7,8
7,11	4,88	1,53	0,56	0,13	0,01	8,4	7,12	4,96	1,52	0,49	0,13	0,02	8,4
7,05	4,46	1,94	0,49	0,12	0,04	7,8	6,85	4,04	2,09	0,57	0,11	0,04	7,8
3,93	3,04	0,64	0,22	0,02	0,01	7,5	3,96	3,1	0,59	0,23	0,03	0,01	7,6
9,57	6,28	2,38	0,75	0,16	0	9,4	9,78	6,42	2,41	0,71	0,22	0,02	9,4
8,65	6,1	1,93	0,56	0,06	0	5,9	8,92	6,48	1,85	0,47	0,09	0,03	5,9
10,86	8,57	1,05	1,13	0,1	0,01	10	11	8,77	1	1,09	0,13	0,01	10
8,32	5,67	1,86	0,51	0,23	0,05	7,8	8,22	5,64	1,83	0,44	0,27	0,04	7,8
8,63	4,88	2,21	0,92	0,61	0,01	9,7	8,57	4,91	2,05	0,94	0,64	0,03	9,7
6,59	4,64	1,17	0,42	0,3	0,06	9,2	6,39	4,52	1,17	0,36	0,28	0,06	9,2
7,89	3,8	3,35	0,61	0,11	0,02	8,3	7,86	3,89	3,34	0,51	0,11	0,01	8,3
6,85	4,6	1,56	0,39	0,28	0,02	8,2	6,91	4,72	1,54	0,4	0,21	0,04	8,2
5,46	2,65	2,09	0,5	0,2	0,02	8,1	5,36	2,64	1,99	0,47	0,24	0,02	8,1
8,47	5,8	1,62	0,61	0,36	0,08	8,5	8,42	5,75	1,68	0,59	0,32	0,08	8,5
9,69	5,38	3,05	1,01	0,23	0,02	8,7	9,85	5,74	3	0,86	0,24	0,01	8,7
8,28	5,1	2,26	0,68	0,2	0,04	7,8	8,03	4,9	2,23	0,67	0,18	0,05	7,8
6,34	3,41	2,17	0,52	0,22	0,02	8,9	6,38	3,28	2,25	0,57	0,23	0,05	8,9
11,76	7,86	2,85	0,73	0,27	0,05	8,9	12,06	7,8	3,09	0,79	0,3	0,08	8,9
6,72	4,65	1,23	0,52	0,29	0,03	7,3	6,78	4,84	1,18	0,43	0,27	0,06	7,3
5,65	3,87	1,13	0,4	0,22	0,03	8,9	5,45	3,64	1,16	0,37	0,25	0,03	8,9
4,08	2,04	1,59	0,35	0,09	0,01	9,8	4,24	2,1	1,68	0,36	0,08	0,02	9,8
6,11	3,07	2,3	0,59	0,12	0,03	9	6,06	3,08	2,3	0,51	0,13	0,04	8,9
14,36	10,32	2,75	1,03	0,24	0,02	9,2	14,72	10,27	3,12	1,08	0,22	0,03	9,3
5,4	2,37	2,39	0,53	0,1	0,01	8	5,45	2,55	2,24	0,55	0,1	0,01	8
9,53	6,53	2,38	0,36	0,21	0,05	8,7	9,58	6,53	2,38	0,44	0,22	0,01	8,6
10,87	8,85	1,3	0,54	0,16	0,02	6,5	10,73	8,71	1,27	0,52	0,21	0,02	6,6
6,21	4,11	1,36	0,62	0,11	0,01	8,8	6,19	3,99	1,44	0,6	0,14	0,02	8,8
6,83	4,26	1,89	0,46	0,18	0,04	6,9	6,94	4,43	1,91	0,42	0,16	0,02	6,9
9,96	6,76	2,35	0,72	0,1	0,03	9,5	10,22	7	2,42	0,68	0,11	0,01	9,5

The dark coloured sample had flags. The sum of neu, eo and baso have been used as ‘true value’ for the granulocytes in Chempaq XBC.

GP B, Venous sample 1 and venous sample 2.

	vene-1	vene-1	vene-1	vene-1	vene-1	vene-1	vene-1	vene-1		vene-2	vene-2	vene-2	vene-2	vene-2	vene-2	vene-2	vene-2
lot	WBC-1	LY-1	MO-1	GR-1	Hb-vene	%LY-1	%MO-1	%GR-1	lot	WBC-2	LY-2	MO-2	GR-2	Hb-vene	%LY-2	%MO-2	%GR-2
112a	11,7	1,4	0,5	9,8	8,2	12,2	4,4	83,4									
112a	7,5	0,8	0,6	6	8,9	11,3	7,7	81									
112a	9,7	1,7	1,1	6,9	6,6	17,4	11,6	71									
112a	10,4	2,5	0,9	7,1	9,3	23,7	8,5	67,8									
112a	5,5	0,9	0,3	4,3	6,3	15,8	5,4	78,8	112a	7,3	1,1	0,4	5,8	7,8	15	5,1	79,9
112a	14,7	1,7	0,8	12,2	7,9	11,5	5,3	83,2									
112a	8,2	1,9	0,6	5,7	9,2	23,2	7,2	69,6									
112a	5,9	1	0,5	4,3	7,7	17,6	8,5	73,9	112a	5,7	1	0,4	4,4	8,1	17	6,8	76,2
112a	10	2	0,7	7,2	7,7	20	7,5	72,5	112a	9,9	1,7	0,7	7,5	7,6	17,4	6,7	75,9
112a	11,7	2	0,6	9,1	7,6	17	5	78	112a	11	2,1	0,7	8,2	7,3	19	6,6	74,3
112a	9,9	1,9	0,6	7,3	8	19,6	6,6	73,9	112a	10,8	1,7	0,6	8,4	7,8	15,9	5,9	78,3
112a	5	1,5	0,4	3	9	30,8	8,2	61	112a	5	1,4	0,4	3,2	9,1	28,2	8	63,8
112a	6,4	2,3	0,6	3,5	8,3	36,5	9,2	54,3	112a	6,8	2,1	0,6	4,1	8,4	30,6	8,9	60,4
112a	8,5	1,5	0,5	6,5	8	18	5,6	76,4	112a	8,9	1,6	0,5	6,8	8,2	17,5	5,7	76,7
112a	6,2	0,6	0,3	5,3	8,1	10	4,1	85,9	112a	5,9	0,5	0,3	5,1	8	9,2	4,3	86,5
112a	10,4	2,5	0,8	7,2	8,1	23,5	7,4	69,1	112a	10,5	2,4	0,7	7,4	8,3	22,9	7,1	70
112a	7,3	1,1	0,4	5,8	8,6	15,6	5,1	79,3	112a	6,8	1,1	0,4	5,3	8,9	16,3	5,4	78,3
112a	5,2	1,5	0,4	3,3	8,6	29,2	8	62,8	112a	5,5	1,5	0,5	3,5	8,2	27,3	8,6	64,2
112a	3,6	1	0,3	2,3	8,6	29,2	8,1	62,7	112a	3,6	1,1	0,3	2,2	8,4	31,6	8,2	60,2
112a	6,5	2,2	0,6	3,7	9,2	33,8	9,4	56,7	112a	6,8	2,3	0,7	3,8	9,6	33,3	10,5	56,3
112a	6,7	2,1	0,6	4,1	8,2	30,5	8,8	60,7	112a	6,7	1,9	0,6	4,2	8,2	28,8	8,5	62,7
112a	4,8	0,9	0,3	3,6	10,1	18,6	6,8	74,6	112a	4,7	0,9	0,3	3,5	10,1	18,9	6,4	74,7
112a	9,3	1,7	0,5	7,1	7,8	18,3	5,4	76,3	112a	9,1	1,8	0,6	6,7	8	20,2	6,2	73,6
112a	8,2	2,3	0,7	5,3	9,7	27,7	8	64,3	112a	8,5	2,5	0,7	5,3	9,6	29,8	8	62,2
112a	5	1,3	0,4	3,2	8,4	26,4	8,6	64,9	112a	5	1,2	0,4	3,4	8,3	24,6	7,2	68,2
112a	6	1,3	0,5	4,2	10,3	21,1	8,5	70,4	112a	6,1	1,4	0,5	4,2	9,7	23,4	7,9	68,7
112a	6,2	1,5	0,5	4,2	7,8	24,6	8,1	67,3	112a	6,2	1,2	0,4	4,5	7,8	20,1	7	72,9
112a	5,2	1,4	0,5	3,3	9,4	26,7	8,7	64,6	112a	5,3	1,2	0,4	3,7	9,7	22,7	7,2	70,1
112a	9,5	2,2	0,7	6,6	9,3	23,6	6,8	69,5	112a	8,7	2,3	0,6	5,8	9,7	25,9	7,3	66,8
112a	7,5	1,8	0,6	5,1	7,8	24,3	8,1	67,6	112a	7,7	1,7	0,6	5,3	8	22,6	7,8	69,6
112a	8,6	1,7	0,6	6,3	9,2	19,3	7,4	73,3	112a	11,9	3,6	0,9	7,4	9,4	29,9	7,7	62,4
112a	11,8	1,3	0,6	9,9	8,9	11,2	4,7	84,1	112a	12	1,6	0,7	9,8	8,8	13,3	5,4	81,3
112a	12,6	1,5	0,8	10,3	9,3	11,6	6,5	82	112a	13,3	1,5	0,9	10,9	9,3	11,2	6,8	81,9
112a	8,8	1,3	0,6	6,9	9,2	14,6	7	78,3	112a	8,9	1,3	0,7	6,9	9,2	14,9	7,7	77,4
115	5,9	1,5	0,5	3,9	8,6	25,2	8,8	66	115	5,8	1,5	0,6	3,7	9,2	26,6	10,1	63,3
115	8,6	1,8	0,7	6,1	10,2	20,9	7,8	71,3	115	8,3	1,8	0,8	5,7	10,1	21,9	9,4	68,7
115	12,1	1,8	0,7	9,6	8,3	14,8	5,9	79,2	115	12	1,9	1	9,1	8,5	15,9	8,1	76
115	8,7	1,5	0,5	6,7	9	16,8	5,8	77,4	115	8,4	1,5	0,5	6,3	8,8	18,3	6,2	75,5
115	8,1	2,5	0,8	4,9	9,1	30,3	9,9	59,8	115	8,6	2,4	0,8	5,4	9	27,6	9,1	63,3
115	6,7	2,1	0,5	4,1	8,9	31,2	7,9	60,9	115	7,1	2,2	0,7	4,3	8,9	30,5	9,4	60,1

The light coloured samples had flags in WBC and the differential. Dark coloured samples: remarks on the performing:

No.5: EDTA glass turned around an extra time

GP B, capillary sample 1 and capillary sample 2.

lot	kap-1 WBC-1	kap-1 LY-1	kap-1 MO-1	kap-1 GR-1	kap-1 Hb-vene	kap-1 %LY-1	kap-1 %MO-1	kap-1 %GR-1	lot	kap-2 WBC-2	kap-2 LY-2	kap-2 MO-2	kap-2 GR-2	kap-2 Hb-vene	kap-2 %LY-2	kap-2 %MO-2	kap-2 %GR-2
112a	no printer								112a	Error 60							
112a	5,4	0,9	0,5	4,1	6,7	16,5	8,3	75,2	112a	2,1	1	0,3	0,9	6,4	45,1	13,3	41,5
112a	11,2	1,9	0,7	8,6	8,9	16,9	6,2	76,8	112a	9,6	1,7	0,7	7,2	7,8	17,8	7,2	75
112a	11,1	2	0,9	8,2	9,6	18,4	8	73,6	112a	11,3	2,9	1,2	7,2	9,9	25,9	10,7	63,4
112a	8,7	1,4	0,5	6,8	8,2	15,9	5,7	78,4	112a	8,1	1,2	0,4	6,4	7,7	15,2	5,5	79,2
112a	13,6	2,3	0,8	10,5	8,3	17,1	5,8	77	112a	13,7	2,3	1	10,4	8	17	7,2	75,8
112a	7,8	1,3	0,6	5,8	8,8	17,2	7,5	75,3	112a	8,1	1,4	0,5	6,1	9	17,8	6,6	75,6
112a	6	1	0,5	4,6	7,9	16,3	8,3	75,4	112a	<1				2,9			
112a	9,8	2,1	0,8	6,9	7,8	21,7	8,2	70,1	112a	3,9	1,3	0,4	2,3	5,6	32,8	9,2	58,1
112a	10,9	2,1	0,9	8	7,4	19,2	7,8	73	112a	Error 60							
112a	11,4	2,3	0,7	8,4	8,2	20	6,2	73,9	112a	11	1,9	0,7	8,3	8,1	17,7	6,5	75,8
112a	4,2	1,4	0,4	2,5	7,7	32,5	8,8	58,7	112a	4,6	1,5	0,4	2,8	9,3	32	8,5	59,5
112a	6,7	2,4	0,6	3,7	8,5	35,9	9,5	54,7	112a	7,2	2,5	0,7	4	8,9	34,7	9,3	56
112a	10,1	1,8	0,6	7,7	9	17,6	6,1	76,3	112a	8	1,6	0,5	5,9	7,1	19,7	6,4	73,9
112a	6,4	0,6	0,3	5,5	8,3	9,7	4,1	86,1	112a	7	0,6	0,3	6,1	8,7	8,6	4,3	87,1
112a	9	2	0,7	6,3	8,2	22,5	8,1	69,5	112a	10,3	2,2	0,6	7,5	8,2	21,3	6,2	72,5
112a	6,7	1,3	0,4	5	8,4	20	5,4	74,6	112a	8,1	1,3	0,5	6,2	9	16,7	6,1	77,2
112a	5,2	1,6	0,4	3,2	8,9	30,1	7,8	62,1	112a	3,9	1,4	0,4	2,1	6,4	36,7	9,7	53,5
112a	4,4	1,8	0,4	2,2	8,9	41	9,3	49,6	112a	4,5	1,5	0,4	2,6	8,6	33,2	9	57,7
112a	7,4	2,5	0,7	4,2	9,7	34,1	9	56,9	112a	7	2,6	0,7	3,7	9,7	37,6	10	52,3
112a	8,2	2,9	0,7	4,6	8,3	34,7	9	56,3	112a	7,7	2,7	0,8	4,2	8,6	35,2	10,2	54,6
112a	5,4	1,1	0,4	3,9	9,6	20,2	8,2	71,7	112a	4,8	0,9	0,3	3,6	9,5	19,5	6,1	74,3
112a	8,2	1,4	0,4	6,4	7,8	17,4	5,3	77,3	112a	8,9	1,5	0,5	6,9	8,1	17	5,9	77
112a	8,2	3	0,8	4,4	9,5	36,8	9,2	54,1	112a	8,8	2,9	0,8	5,1	9,6	33,3	8,7	58
112a	5,7	1,4	0,4	3,9	8,5	24,6	6,7	68,7	112a	5,1	1,3	0,4	3,4	8,6	25,9	6,9	67,2
112a	8,1	1,8	0,7	5,6	10,2	22,2	8,3	69,5	112a	6,6	1,8	0,6	4,4	10,3	23,5	9,6	66,9
112a	6,2	1,2	0,5	4,5	7,4	19,2	8,1	72,7	112a	7,8	2,1	0,6	5,2	8,7	26,4	7,2	66,4
112a	5,8	1,5	0,5	3,7	9,3	26,6	8,4	64,9	112a	5,3	1,4	0,5	3,5	9,4	25,9	9	65,1
112a	8,9	2,3	0,7	5,8	9,8	26	8,1	65,9	112a	9,3	2,5	0,7	6,1	9,9	26,9	7,6	65,4
112a	7,8	1,8	0,6	5,4	8	23,6	7,8	68,7	112a	7,1	1,6	0,5	5	8,2	22,6	7,2	70,2
112a	8,5	1,9	0,6	6	9	22,7	6,7	70,6	112a	Error 60							
112a	12,4	1,7	0,7	10	8,8	13,5	5,7	80,7	112a	12,2	1,6	0,7	9,9	9,2	12,9	5,5	81,5
112a	11,2	1,2	0,6	9,4	8,7	10,5	5,4	84,1	112a	11,1	1,3	0,8	9	8,9	11,6	7	81,4
112a	9,8	1,5	0,6	7,7	9,2	15,2	5,8	79	112a	9,2	1,5	0,4	7,3	9	15,8	4,9	79,3
115	5,7	1,6	0,6	3,5	9,2	29,1	9,8	61,1	115	5,4	1,5	0,5	3,3	8,9	28,7	9,5	61,8
115	Error 60								115	10,7	2	0,7	8	10,1	18,5	6,6	74,9
115	12,4	1,8	0,7	9,9	8,3	14,4	5,6	79,9	115	12,6	2,3	1,2	9,1	8,5	18,3	9,7	72
115	8,5	1,8	0,6	6,2	8,4	20,8	7,1	72,1	115	9	1,7	0,7	6,6	8,7	18,8	8	73,2
115	7,9	2,4	0,9	4,6	9,6	30,8	11,4	57,8	115	8,7	2,4	0,9	5,5	9,8	27,3	9,8	62,9
115	7,5	2,4	0,7	4,3	9,2	32,6	9,9	57,5	115	6,7	2,1	0,7	3,9	9,1	31,9	10,1	58

The light coloured samples had flags in WBC and the differential. Dark coloured samples: remarks on the performing: No.2: difficult to get a blood drop.

Sysmex comparison result 1 and result 2 for GP B

WBC-1	NEU-1	LY-1	MO-1	EO-1	BASO-1	Hb-vene	WBC-2	NEU-2	LY-2	MO-2	EO-2	BASO-2	Hb-vene
9,83	7,05	1,94	0,62	0,19	0,03	8,3	9,78	6,95	1,91	0,68	0,17	0,07	8,4
6,35	4,38	1,6	0,35	0,02	0	8,6	6,09	3,91	1,75	0,4	0,03	0	8,6
Coagulation							Coagulation						
8,58	3,72	3,74	0,98	0,13	0,01	9,4	8,71	3,96	3,63	0,92	0,15	0,05	9,4
6,33	4,77	1,21	0,28	0,04	0,03	7,7	6,21	4,47	1,34	0,35	0,04	0,01	7,7
12,09	8,87	2,28	0,52	0,41	0,01	8	11,98	8,63	2,31	0,52	0,5	0,02	8
6,87	3,78	2,26	0,68	0,13	0,02	8,9	7,05	4,07	2,18	0,64	0,14	0,02	8,9
5,44	3,67	0,92	0,75	0,1	0	7,7	5,44	3,7	0,9	0,74	0,09	0,01	7,6
8,02	4,46	2,09	1,2	0,26	0,01	7,5	8,2	4,72	1,98	1,24	0,24	0,02	7,5
9,95	7,37	1,87	0,49	0,17	0,05	7	10,14	7,78	1,69	0,43	0,14	0,1	7,1
8,99	6,35	1,9	0,59	0,11	0,04	7,5	9,02	6,44	1,8	0,61	0,11	0,06	7,5
4,31	2,06	1,74	0,37	0,11	0,03	8,6	4,21	2,14	1,57	0,35	0,12	0,03	8,5
5,54	2,73	2,09	0,5	0,17	0,05	8	5,73	2,92	2,08	0,51	0,18	0,04	8
7,09	4,68	1,76	0,37	0,23	0,05	7,8	7,15	4,56	1,91	0,38	0,26	0,04	7,8
5,46	4,23	0,68	0,47	0,07	0,01	7,7	5,35	4,11	0,62	0,52	0,09	0,01	7,6
8,86	5,93	2,32	0,46	0,11	0,04	7,7	8,87	5,85	2,34	0,52	0,11	0,05	7,7
5,73	3,87	1,48	0,26	0,1	0,02	8,2	5,77	3,89	1,58	0,2	0,09	0,01	8,2
5,07	2,62	1,75	0,42	0,23	0,05	7,7	5,13	2,67	1,75	0,45	0,23	0,03	7,7
3,21	1,51	1,22	0,38	0,08	0,02	8	3,22	1,64	1,15	0,34	0,08	0,01	8,1
5,92	2,78	2,28	0,4	0,43	0,03	8,8	5,86	2,64	2,29	0,37	0,52	0,04	8,8
5,83	2,72	2,38	0,55	0,15	0,03	7,7	6,02	3,02	2,33	0,52	0,14	0,01	7,8
4,42	3,15	0,86	0,33	0,07	0,01	9,3	4,47	3,12	0,91	0,37	0,07	0	9,2
8,03	5,62	1,97	0,41	0,02	0,01	7,3	8,14	5,69	1,99	0,42	0,03	0,01	7,4
7,89	4,33	2,68	0,54	0,3	0,04	8,9	7,75	4,06	2,83	0,54	0,29	0,03	8,9
4,62	2,96	1,18	0,38	0,08	0,02	7,8	4,74	3,1	1,15	0,39	0,08	0,02	7,7
5,69	4,09	1,17	0,39	0,03	0,01	9,6	5,8	4,09	1,25	0,41	0,04	0,01	9,6
5,04	2,86	1,68	0,41	0,05	0,04	7,4	5,21	3,01	1,72	0,41	0,05	0,02	7,4
4,58	2,82	1,36	0,28	0,12	0	8,8	4,44	2,63	1,39	0,3	0,1	0,02	8,8
7,58	4,27	2,44	0,5	0,35	0,02	8,9	7,88	4,68	2,38	0,44	0,36	0,02	8,9
6,01	3,44	1,67	0,73	0,15	0,02	7,4	6,22	3,69	1,76	0,62	0,13	0,02	7,4
7,1	4,76	1,47	0,66	0,16	0,05	8,8	7,27	4,72	1,6	0,74	0,18	0,03	8,8
10,05	7,71	1,58	0,69	0,07	0	8,1	10,17	7,89	1,52	0,7	0,06	0	8,1
10,65	8,22	1,25	0,95	0,21	0,02	8,8	10,77	8,37	1,24	0,97	0,15	0,04	8,8
7,73	5,85	1,44	0,34	0,09	0,01	8,5	7,77	5,71	1,51	0,43	0,11	0,01	8,5
5,22	3,22	1,5	0,39	0,09	0,02	8,5	5,17	3,23	1,5	0,35	0,08	0,01	8,5
7,18	4,72	1,73	0,54	0,14	0,05	9,5	7,36	4,94	1,8	0,42	0,17	0,03	9,5
9,97	7,41	1,76	0,66	0,12	0,02	7,8	9,71	7,51	1,48	0,6	0,11	0,01	7,8
7,26	4,7	1,69	0,74	0,11	0,02	8,2	7,27	4,58	1,76	0,74	0,13	0,06	8,2
6,75	3,85	2,16	0,52	0,19	0,03	8,6	6,87	3,87	2,28	0,5	0,2	0,02	8,6
6,08	3,24	2,04	0,65	0,15	0	8,5	6,18	3,43	2,07	0,57	0,1	0,01	8,5

The dark coloured sample had flags. The sum of neu, eo and baso have been used as ‘true value’ for the granulocytes in Chempaq XBC.

Rawdata Primary Care Evaluation II

GP A Capillary samples

lot	WBC-1	LY-1	MO-1	GR-1	Hb-ven	%LY-1	%MO-1	%GR-1		WBC-2	LY-2	MO-2	GR-2	Hb-ven	%LY-2	%MO-2	%GR-2
131	5,6	1,7	0,4	3,4	9,6	30,6	7,9	61,5	131	5,3	1,4	0,4	3,6	9,7	25,7	6,8	67,4
131	8,7	1,6	0,6	6,4	9,8	18,6	7,5	74	131	7,9	1,3	0,4	6,2	10	16,1	5,5	78,4
131	6,5	1,8	0,4	4,3	9,5	27,2	6,8	66,1	131	5,6	1,8	0,5	3,3	9,5	32,4	8,8	58,8
131	5,4	2	0,5	2,9	8,9	37,4	9,2	53,5	131	5	1,9	0,5	2,6	8,7	38,4	9,7	52
131	7	1,6	0,4	5,1	8,8	22,1	6	71,9	131	6,1	1,6	0,5	4	8,3	25,8	8,6	65,6
131	6,1	1,1	0,5	4,5	9,8	18,5	8,5	73	131	5,9	1,2	0,5	4,2	10,1	20,4	8,4	71,2
131	7,3	2,9	0,6	3,8	9	39,5	8,4	52	131	6,2	2,6	0,6	3	8,8	42	9,8	48,1
131	5,3	1,4	0,4	3,5	7,7	26,5	8	65,5	131	5,5	1,4	0,5	3,6	8	26,3	8,5	65,2
131	5,3	1,3	0,5	3,6	10	23,5	8,8	67,7	131	4,4	1	0,3	3,1	9,1	23,7	6,6	69,7
131	5,5	2	0,5	2,9	10,4	37	9,4	53,5	131	6	2,1	0,6	3,3	10,3	35,3	10	54,7
131	8,7	3	0,8	4,8	7,3	35,1	9,4	55,5	131	7,5	2,9	0,7	3,8	7,2	39,3	9,7	51
131	6,2	2,3	0,7	3,2	9	37,7	10,8	51,5	131	5,2	1,8	0,5	2,9	8,5	34,8	10,2	55
131	7,2	1,5	0,7	5	8,6	21	9,9	69	131	7,4	1,4	0,6	5,3	8,8	19,2	8,7	72,1
131	9,4	3,5	1	5	9,7	37,1	10,3	52,7	131	10,2	3,7	1	5,5	10	36,6	9,6	53,9
131	9,4	2,6	0,9	5,9	8,8	27,3	9,1	63,6	131	9,5	3,2	0,9	5,4	8,4	33,6	9,9	56,4
131	5,6	1,4	0,5	3,7	9,8	25,5	9,3	65,2	131	6,4	1,5	0,6	4,4	10,3	23,2	8,9	67,9
131	10	1,2	0,9	7,9	8,7	11,7	8,8	79,5	131	11,1	1,2	1	8,9	9	10,8	8,7	80,5
131	8	2,7	0,7	4,5	10,5	34,2	9	56,8	131	5,6	1,9	0,5	3,2	9,9	33,3	9,4	57,3
131	4,3	1,4	0,4	2,5	9	33,5	9,3	57,1	131	3,7	1,2	0,3	2,2	8,9	32,1	8,8	59,1
131	4	1,2	0,4	2,4	2,2	28,9	10	61,1	131	10,3	2,4	0,8	7,1	8,6	23,2	7,8	69
131	3,7	1,4	0,4	1,9	9,4	39	10,4	50,6	131	3,4	1,2	0,3	1,8	9,1	35,6	10,3	54,1
131	4,5	1,4	0,4	2,7	9,3	30,6	9,5	59,9	131	4,2	1,3	0,4	2,5	9	31	10	59,1
131	8,9	2,1	0,8	5,9	11,3	24,2	9,4	66,5	131	8,1	1,9	0,8	5,4	10,8	23,5	9,4	67,1
131	5,3	1,9	0,5	2,9	9,7	36,4	10,2	53,4	131	5,5	1,9	0,5	3,1	9,7	34,2	9,4	56,4
131	9,7	1,6	0,8	7,2	7	16,6	8,7	74,6	131	9	1,5	0,8	6,7	6,8	16,9	9,1	74
131	5,1	1,7	0,5	2,9	9,4	34,1	8,8	57,1	131	5,1	2	0,5	2,6	9,3	38,6	10,7	50,7
131	5,1	1,2	0,4	3,6	9,9	22,9	7,3	69,7	131	5,3	1,2	0,5	3,6	9,8	23,4	8,7	67,9
131	7,2	1,7	0,6	4,9	8,6	24,3	8,1	67,6	131	7,7	1,9	0,7	5,1	9,4	24,8	8,7	66,5
131	7,8	1,5	0,6	5,7	10,4	18,7	7,9	73,3	131	7,1	1,3	0,6	5,1	9,8	18,6	8,7	72,8
131	5,9	1,7	0,5	3,6	10,2	29,6	8,9	61,6	131	4,5	1,5	0,4	2,7	9,4	32,1	9,6	58,3
131	6,5	1,6	0,5	4,4	9,4	24,9	7,9	67,2	131	6,6	1,7	0,5	4,4	9,4	25,4	6,9	67,6
131	6,4	1,7	0,5	4,3	9,9	25,9	7,7	66,4	131	6	1,5	0,5	4,1	9,7	24,4	7,6	68
131	4,6	1,1	0,4	3,1	8,6	24,2	9,2	66,6	131	4,1	1	0,4	2,7	7,9	25,2	9,3	65,6
131	8,1	2,3	0,8	5	8,2	28,6	9,8	61,6	131	7,5	2	0,7	4,9	8,3	26,7	8,7	64,5
131	6,8	1,6	0,6	4,6	9,4	23,9	8,9	67,1	131	6,6	1,8	0,6	4,2	9,1	27,4	9,2	63,4
131	7,5	2,6	0,7	4,3	8,1	34,8	8,7	56,6	131	7,6	2,5	0,7	4,4	8	32,8	9,3	58
131	5,3	1,4	0,5	3,4	9,5	26,6	10	63,4	131	4,7	1,4	0,4	2,8	9,4	31	9,4	59,5
131	4,8	2,1	0,5	2,2	7,5	45	9,7	45,3	131	4,8	1,9	0,4	2,4	7,9	40,5	9,2	50,3
131	8,2	2,8	0,7	4,7	9	34,1	8,7	57,2	131	7,3	2,3	0,7	4,3	9,4	31,6	9,4	59
131	3,7	1,4	0,4	1,9	10,2	39	10	51	131	4	1,3	0,4	2,3	10,7	32,6	9,1	58,3

yellow sample: difficulties in blood sampling

GP A Venous samples

lot	WBC-1	LY-1	MO-1	GR-1	Hb-1	%LY-1	%MO-1	%GR-1	lot	WBC-2	LY-2	MO-2	GR-2	Hb-2	%LY-2	%MO-2	%GR-2
131	5,4	1,5	0,4	3,5	9,5	28,1	7,7	64,2	131	5,2	1,4	0,5	3,3	9,6	27,2	9,1	63,6
131	7,5	1,5	0,5	5,5	9,8	19,8	7	73,2	131	7,5	1,5	0,6	5,4	10	20,3	8,5	71,2
131	5,8	1,5	0,5	3,8	9,6	25,6	9	65,3	131	6,2	1,5	0,4	4,2	9,7	24,8	6,9	68,3
131	5,2	1,9	0,4	2,9	8,5	36,5	8,6	54,9	131	4,9	2	0,4	2,4	8,5	41,4	8,7	49,9
131	6	1,6	0,5	3,9	8,4	25,8	9	65,2	131	6,3	1,5	0,6	4,2	8,4	23,6	9,2	67,2
131	6,5	1,4	0,6	4,5	10,6	21,4	9,6	68,9	131	6,4	1,2	0,5	4,7	10,2	18,7	8	73,3
131	7,3	2,9	0,7	3,7	9,1	39,6	9,6	50,7	131	7,3	2,8	0,7	3,8	9	39	9,5	51,5
131	5	1,3	0,5	3,2	7,8	26,9	10,4	62,7	131	5	1,5	0,5	2,9	7,6	30,9	11	58,1
131	4,7	1,1	0,3	3,3	9,4	23,1	6,6	70,4	131	4,4	1,3	0,5	2,7	9,5	28,7	10,4	60,9
131	5,2	2	0,6	2,7	10	38,2	10,6	51,2	131	5,4	1,9	0,6	2,9	10,1	35,7	10,3	54
131	4,3	1,3	0,4	2,6	9	30,4	9,5	60,1	131	4,4	1,3	0,4	2,8	8,9	28,8	9,1	62,1
131	10,7	2,5	1	7,2	8,5	23,4	9,3	67,3	131	11,2	2,4	1	7,8	8,4	21,5	9	69,5
131	3,5	1,4	0,4	1,8	9,3	39,2	10,2	50,6	131	3,5	1,2	0,4	1,9	9,4	35	10,1	54,9
131	4,4	1,3	0,4	2,7	9,3	29,3	9,9	60,8	131	4,4	1,3	0,4	2,7	9,2	28,6	10	61,4
131	8,2	2	7	5,5	10,9	24,3	8,9	66,8	131	8,2	1,8	0,7	5,7	10,8	21,9	8,2	69,9
131	5,5	1,9	0,5	3	9,7	35,4	9,4	55,2	131	5,5	1,9	0,6	3,1	9,7	34,1	10	55,9
131	9,3	1,8	1	6,6	6,8	18	10,2	71	131	9,1	1,7	0,8	6,6	6,5	18,6	8,7	72,7
131	5,1	1,9	0,5	2,7	9,4	37,6	10,3	52,1	131	5,3	2	0,5	2,9	9,1	36,9	9,4	53,7
131	5,3	1,3	0,5	3,5	9,6	25,1	10	64,9	131	5,3	1,4	0,4	3,5	9,5	26,4	8,1	65,5
131	7,3	2,1	0,7	4,4	8,8	29,5	9,3	61,2	131	7,5	2,1	0,7	4,7	9	27,6	9,3	63,1
131	7	1,2	0,7	5,1	9,7	17,8	9,8	72,4	131	7,1	1,4	0,7	5	9,8	19,6	9,8	70,6
131	5,2	1,7	0,5	3,1	9,9	31,7	9,7	58,6	131	5,3	1,7	0,5	3,1	10	32,1	9,6	58,3
131	6	1,6	0,5	3,9	9,8	26,4	8,5	65	131	6	1,4	0,5	4,1	9,7	23	8,8	68,2
131	7	1,7	0,6	4,7	9,7	24,4	8,1	67,6	131	6,7	1,7	0,6	4,4	9,6	25,4	9	65,6
131	4	1	0,4	2,6	8,4	26	9,5	64,4	131	3,8	1	0,4	2,4	8,1	27	10	62,9
131	8,5	2,1	0,7	5,6	8,3	25	8,7	66,3	131	7,7	2,2	0,7	4,8	8,2	28,5	9,5	61,9
131	6	1,7	0,5	3,8	9,3	29	8,5	62,5	131	6,3	1,5	0,5	4,3	9,4	23,2	8,4	68,4
131	7,4	2,4	0,7	4,3	8,4	32,1	9,5	58,4	131	7,8	2,3	0,7	4,8	8,5	29,6	8,7	61,6
131	5,1	1,4	0,5	3,2	9,3	28,3	9,3	62,3	131	5	1,5	0,5	3,1	9	28,8	9,4	61,8
131	4,7	1,7	0,4	2,5	7,8	37,2	8,9	53,9	131	4,7	2	0,5	2,3	7,7	41,8	9,9	48,3
131	7,2	2,5	0,7	4	9,3	34,8	9,3	55,9	131	7,6	2,4	0,7	4,5	9,4	31,5	9,3	59,2
131	3,6	1,2	0,4	2	10,1	33,6	10,7	55,8	131	3,5	1,2	0,4	2	10,2	33,3	10,4	56,3

GP A Results from comparison method: Coulter

WBC-1	NEU-1	LY-1	MO-1	EO-1	BASO-	Hb-ven	WBC-2	NEU-2	LY-2	MO-2	EO-2	BASO-	Hb-ven
5,5	2,7	2,1	0,5	0,1	0	9,1	5,5	2,7	2,1	0,5	0,2	0	9,1
7,6	5	1,9	0,5	0,2	0	9,7	7,6	4,9	1,9	0,6	0,2	0	9,7
5,9	3	1,8	0,6	0,5	0	9,6	5,8	3	1,8	0,5	0,5	0	9,6
4,7	2	2	0,4	0,2	0	8,5	4,8	2,1	2	0,4	0,2	0	8,5
6,6	3,6	1,7	0,5	0,8	0	8,4	6,6	3,6	1,7	0,4	0,8	0,1	8,4
6,5	4,3	1,5	0,5	0,2	0	10,3	6,4	4,2	1,5	0,4	0,3	0	10,2
6,9	2,8	3,1	0,8	0,1	0	8,9	6,8	2,8	3,1	0,8	0,1	0	8,8
5,3	3,2	1,6	0,4	0,1	0,1	7,5	5,2	3,2	1,5	0,3	0,1	0,1	7,5
4,7	2,9	1,4	0,3	0,1	0	9,5	4,7	3	1,3	0,3	0,1	0	9,5
						9,7							9,7
6,9	3,4	2,9	0,3	0,1	0,1	6,7	6,8	3,3	2,9	0,4	0,1	0,1	6,7
5,5	3,1	1,8	0,5	0,1	0,1	8,5	5,6	3,1	1,9	0,4	0,1	0	8,5
7,6	5,6	1,4	0,5	0,1	0	8,7	7,7	5,7	1,3	0,5	0,1	0	8,7
9,5	5	3,7	0,6	0,1	0	10	9,7	5,2	3,6	0,7	0,1	0	10
9,4	5,4	3,1	0,6	0,2	0	8,3	9,6	5,7	3,1	0,6	0,2	0,1	8,3
6	3,7	1,5	0,6	0,2	0	9,8	6	3,7	1,5	0,6	0,2	0	9,8
10,4	8,7	1	0,4	0,2	0	8,7	10,2	8,4	1,1	0,5	0,2	0	8,7
6,3	2,7	2,4	0,7	0,4	0,1	9,7	6,2	2,7	2,3	0,7	0,5	0	9,8
4,1	2,1	1,5	0,3	0,2	0	8,7	4,1	2,2	1,5	0,3	0,2	0	8,7
10	6,4	2,6	0,5	0,5	0	8,5	10	6,3	2,7	0,6	0,4	0	8,5
3,7	2	1,5	0,2	0	0	8,9	3,8	2	1,5	0,2	0,1	0	9,2
4,6	2,5	1,4	0,5	0,1	0	9	4,7	2,5	1,5	0,5	0,1	0	9
8,9	5,8	2,5	0,5	0,1	0	10,6	8,8	5,6	2,6	0,5	0,1	0,1	10,6
5,5	2,8	2,2	0,4	0,1	0	9,4	5,6	2,8	2,2	0,5	0,1	0	9,4
10,1	7,7	1,5	0,4	0,3	0	6,9	10	7,6	1,6	0,4	0,3	0	6,9
5,1	2,3	2,2	0,5	0,1	0	9	5,2	2,3	2,2	0,5	0,1	0	9
4,9	3,2	1,4	0,2	0	0	9,4	5,1	3,2	1,5	0,2	0,1	0	9,4
7,3	4,5	2	0,7	0,1	0	8,8	7,3	4,5	1,9	0,7	0,1	0,1	8,8
6,9	4,8	1,4	0,5	0,1	0	9,5	6,9	4,8	1,5	0,5	0,1	0	9,5
5,4	2,9	1,9	0,5	0,1	0	9,7	5,4	2,9	1,8	0,5	0,1	0	9,7
6,1	3,8	1,7	0,4	0,1	0	9,4	6,1	3,8	1,8	0,4	0,1	0	9,4
6,5	3,9	1,9	0,5	0,2	0	9,2	6,5	3,9	1,9	0,5	0,2	0	9,3
4	2,6	1	0,3	0,1	0	8,1	4,1	2,6	1	0,3	0,1	0	8,1
7,5	4,4	2,2	0,6	0,3	0	8	7,7	4,5	2,2	0,6	0,4	0	8
6	3,5	1,8	0,5	0,3	0	9	6,3	3,6	1,9	0,5	0,3	0	9
7,7	4,5	2,7	0,4	0,1	0	7,9	7,5	4,6	2,5	0,4	0,1	0	7,9
5,1	2,9	1,6	0,4	0,1	0	9,1	5	3	1,6	0,4	0,1	0	9,1
4,5	1,9	2	0,3	0,2	0	7,6	4,5	1,9	2	0,4	0,2	0	7,7
7,4	4	2,7	0,4	0,2	0	9	7,4	4,1	2,6	0,4	0,2	0	9,1
3,7	1,7	1,4	0,4	0,1	0	10	3,8	1,8	1,5	0,4	0,1	0	10

Result from sample no 10: Analysed after 23 hours.

GP 2 Capillary samples

lot	WBC-1	LY-1	MO-1	GR-1	Hb-vene	%LY-1	%MO-1	%GR-1		WBC-2	LY-2	MO-2	GR-2	Hb-vene	%LY-2	%MO-2	%GR-2
131	5,3	1,7	0,5	3,2	8,9				131	5,6	1,8	0,6	3,2	8,6	32,6	10,3	57,1
131	4	0,9	0,4	2,7	5,8	21,9	9,5	68,6	131	5	1	0,5	3,5	8	20,6	9,2	70,2
131	5,9	1,3	0,6	4,1	9,2	21,2	9,4	69,4	131	5,1	1	0,4	3,7	8,5	19,5	8,1	72,4
131	5,7	1,5	0,5	3,7	8,6	26	9,3	64,7									
131	11,1	3,2	1,2	6,6	10,2	29,3	11,1	59,6	131	11,3	2,8	1	7,5	10,5	24,8	9,1	66,1
131	10,4	3,2	1	6,2	9,7	30,9	10	59,2	131	10,5	3,3	0,9	6,3	9,2	31,3	8,9	59,8
131	7,9	1,8	0,6	5,5	8,7	23,2	8	68,8	131	7,3	2	0,7	4,6	8,3	27,4	9,3	63,3
131	10	2	1	7	8,7	20,3	9,9	69,8	131	9,1	1,9	0,9	6,2	8,2	21,3	9,9	68,8
131	5,8	2,6	0,6	2,6	10,2	44,9	10,9	44,2	131	5,4	2,4	0,5	2,4	10,3	44,7	10,2	45,1
131	7,9	2,1	0,8	4,9	8,8	27,3	9,9	62,8	131	6,9	2,1	0,7	4,2	7,9	30,1	9,4	60,5
131	8,6	3,3	0,9	4,4	9,7	38,8	10,4	50,8	131	8,5	3,1	0,9	4,5	9,2	36,5	10,5	53
131	7,4	1,4	0,6	5,4	7,8	18,5	8,2	73,3	131	7,3	1,5	0,7	5,1	7,8	21,1	9,1	69,8
131	5	1,7	0,5	2,7	9,5	34,7	9,9	55,4	131	4,2	1,5	0,4	2,3	9,4	36,7	8,9	54,4
131	7,7	1,8	0,5	5,4	9,1	23,6	7,1	69,4	131	8,1	1,9	0,7	5,5	9,5	23,8	8,1	68,1
131	6,4	2,1	0,7	3,6	9,8	33,2	10,2	56,6	131	5	1,7	0,5	2,7	9,7	34,8	9,8	55,3
131	6,5	1,8	0,6	4,1	8,8	27	9,9	63,1	131	6,2	1,6	0,6	4	8,7	26,3	9,5	64,3
131	7	2,5	0,6	3,9	7,2	35,6	9,2	55,2	131	7,8	2,6	0,8	4,4	7,2	33,5	10,4	56,1
131	6,6	2,7	0,7	3,3	8,4	40,4	9,9	49,7	131	5,6	2,2	0,6	2,7	8,3	40,1	10,4	49,4
131	7,6	2,4	0,8	4,4	8,7	31,9	10,5	57,6	131	6,6	2	0,7	3,9	8,8	30,8	10,8	58,4
131	6,4	1,4	0,6	4,3	9,7	22	9,6	68,4	131	6,1	1,5	0,6	4	9,9	24,6	9,5	65,9
131	6	1,8	0,6	3,6	9,4	29,8	10,3	59,9	131	6,2	2	0,7	3,5	10	31,8	11,3	56,9
131	5,3	1,8	0,5	2,9	8,6	34,7	9,6	55,7	131	6,3	2,1	0,5	3,7	8,3	32,9	8,3	58,8
131	8,6	1,3	0,8	6,5	8,8	15,4	8,9	75,7	131	8,1	1,6	0,9	5,6	9,2	19,3	11,1	69,6
131	7,6	2,3	0,7	4,6	9,1	29,5	9,5	61	131	6,8	1,8	0,6	4,3	8,9	26,9	9	64,1
131	8,7	1,9	0,8	6	10,3	21,3	9,4	69,4	131	8,8	1,8	0,7	6,3	10,3	20,2	7,8	72
131	6,6	2,6	0,7	3,3	8,8	39,5	10,2	50,3	131	6,1	2,4	0,6	3,1	8,5	38,5	10,4	51,2
131	5,8	2	0,6	3,3	9,1	34,6	9,4	56	131	5,4	1,9	0,5	2,9	9	36	9,7	54,3
131	6	1,3	0,7	4	8	22,1	10,9	66,9	131	6,8	1,3	0,7	4,8	8,6	18,9	9,8	71,3
131	9	1,7	0,8	6,5	10,3	18,9	9,2	71,9	131	10,2	2	0,8	7,3	10,6	19,9	8,3	71,9
131	8,6	2,3	0,8	5,5	7	26,8	9	64,3	131	10,1	2,7	0,9	6,5	6,8	26,3	9,2	64,5
131	5,6	1,4	0,5	3,6	8,6	25,3	9,5	65,2	131	5,7	1,4	0,5	3,8	8,9	24,6	9	66,5
131	11,8	1,8	1,1	8,9	8,5	15,4	9,5	75,1	131	11,5	2,4	1,1	8	9	21,1	9,6	69,3
131	10,5	3,3	1,1	6,1	9,1	31,1	10,6	58,3	131	11,5	3,1	1,1	7,3	9,6	27,2	9,7	63,1
131	6,2	1,9	0,6	3,7	9,1	30,1	9,9	60	131	5,9	1,7	0,6	3,6	8,7	29,1	9,8	61,1
131	4,4	1,3	0,4	2,6	7,7	30,3	9,7	60	131	4,3	1,3	0,4	2,5	7,6	31,3	9,8	58,9
131	8,5	3,4	0,8	4,2	8	40,5	9,6	49,9	131	7,3	2,4	0,6	4,3	8,1	32,5	8,8	58,7
131	6,7	1,6	0,6	4,5	9,6	23,5	9,2	67,4	131	7,5	1,5	0,6	5,3	10,3	20,8	8,6	70,7
131	16,4	2,8	1,2	12,4	7,5	16,8	7,4	75,8	131	15,5	2,9	1,2	11,4	7,5	18,5	7,8	73,7
131	6,3	1	0,7	4,6	9,5	15,8	10,9	73,3	131	6,4	1	0,6	4,8	9,4	14,9	9,8	75,3
131	6,2	2,1	0,6	3,4	8,8	34,3	10,2	55,5	131	5,5	2	0,5	3	8,4	35,9	9,4	54,8
131	5,6	1,1	0,5	4	9	19,5	8,2	72,2	131	4,9	1	0,4	3,5	8,5	20,4	8,7	70,9
131	4,3	1,3	0,4	2,6	9	30	9,1	60,9	131	4	1,2	0,4	2,3	8,6	31,1	9,5	59,3

Yellow samples: Cold finger.
Purple: Error code ’60’ x 2, patient had left.

GP B Results from comparison method: Coulter

WBC-1	NEU-1	LY-1	MO-1	EO-1	BASO-1	Hb-vene	WBC-2	NEU-2	LY-2	MO-2	EO-2	BASO-2	Hb-vene
5,3	2,9	1,8	0,4	0,2	0	8,3	5,3	2,9	1,8	0,4	0,2	0	8,2
5,5	4	1,1	0,2	0,1	0	8,1	5,4	4	1,1	0,2	0,1	0	8,1
5,8	4	1,3	0,4	0,1	0	8,9	5,8	3,9	1,3	0,4	0,1	0	8,9
6,1	3,5	2	0,6	0,1	0	8,8	6,2	3,5	2	0,6	0,1	0	8,8
11,4	7	3	0,8	0,4	0,1	10,2	11,3	7	3	0,8	0,5	0,1	10,2
9,4	5,8	2,8	0,7	0,1	0,1	9,4	9,4	5,9	2,8	0,7	0,1	0,1	9,5
7,4	4,9	1,8	0,5	0,1	0	8,2	7,7	5,2	1,9	0,5	0,1	0	8,1
8,9	6,6	1,9	0,4	0	0	8,4	8,9	6,6	1,8	0,4	0	0	8,5
5,5	2,2	2,5	0,6	0,1	0	10,1	5,8	2,4	2,6	0,7	0,1	0	10
6,9	4,3	1,9	0,4	0,3	0	8	6,8	4,2	1,9	0,4	0,3	0	7,9
7,7	3,9	2,9	0,4	0,4	0	8,8	7,6	3,9	2,9	0,4	0,4	0	8,9
6,5	4,7	1,3	0,5	0,1	0	7,9	6,5	4,6	1,3	0,5	0,1	0	8
4,3	2,1	1,6	0,3	0,2	0	9	4,3	2,2	1,6	0,3	0,2	0	9,1
7,5	4,8	2	0,5	0,3	0	8,9	7,6	4,8	2	0,4	0,3	0	8,9
5,1	2,4	2	0,5	0,2	0	9,1	5,1	2,4	2	0,5	0,2	0	9
6,8	4,3	1,8	0,5	0,1	0	8,6	6,8	4,2	1,9	0,5	0,1	0	8,6
8,1	4,7	2,7	0,5	0,1	0	7,5	8,1	4,7	2,8	0,5	0,1	0	7,5
5,9	3,2	2,3	0,4	0,1	0	8,3	6	3,2	2,3	0,4	0,1	0	8,3
6,4	3,9	1,8	0,6	0,1	0	8,7	6,4	3,9	1,7	0,6	0,1	0	8,7
6	3,6	1,4	0,8	0,1	0	9,6	6,1	3,7	1,4	0,8	0,1	0	9,6
6,6	4	1,9	0,4	0,2	0	9,7	6,9	4	2,1	0,5	0,2	0	9,8
5,3	2,4	1,9	0,5	0,1	0	8,2	5,2	2,7	1,9	0,5	0,1	0	8,3
8	5,7	1,5	0,7	0,1	0	8,6	8,3	6	1,4	0,7	0,1	0	8,7
7,2	4,2	2,3	0,5	0,2	0	9	7,2	4,1	2,3	0,4	0,3	0,1	9
8,7	5,8	2	0,8	0,1	0	10,3	8,8	5,9	1,9	0,9	0,1	0	10,3
7,3	3,9	2,7	0,6	0,1	0	8,7	7,3	3,8	2,7	0,6	0,1	0	8,7
5,1	2,6	1,8	0,6	0,2	0	8,7	5,1	2,6	1,8	0,5	0,2	0	8,8
6,5	4,7	1,2	0,4	0,1	0	8,3	6,7	4,9	1,2	0,4	0,1	0	8,4
8	5,5	1,5	0,6	0,4	0,1	10	8	5,4	1,5	0,7	0,4	0,1	10
6,3	4,3	1,4	0,4	0,2	0	6,8	6,3	4,3	1,4	0,4	0,2	0	6,8
5,8	3,9	1,3	0,5	0	0	9	5,8	3,9	1,3	0,5	0	0	9,1
10	7,5	1,6	0,6	0,1	0	8	10	7,6	1,5	0,7	0,1	0	8
10,2	6,2	2,9	0,5	0,1	0	9,3	10,2	6,1	3	0,5	0,4	0,1	9,3
6	3,4	1,6	0,5	0,3	0,1	9,1	5,9	3,5	1,6	0,5	0,3	0,1	9,1
4,2	2,4	1,2	0,6	0,1	0	8	4,3	2,5	1,1	0,6	0,1	0	8
6,2	3,3	2,3	0,4	0,2	0	7,5	6,2	3,3	2,3	0,3	0,1	0	7,6
7,2	4,7	1,7	0,7	0,1	0	9,7	7,3	4,7	1,6	0,8	0,1	0	9,7
15	11,7	2,6	0,5	0,2	0	7,3	15,1	11,6	2,6	0,7	0,2	0	7,3
6,4	5,4	0,6	0,3	0	0	9,3	6,4	5,5	0,6	0,3	0	0	9,4
5,3	3,1	1,7	0,4	0,1	0	8,2	5,4	3,2	1,6	0,5	0,1	0	8,2
6	4,2	1,3	0,4	0,1	0	8,4	6,1	4,2	1,3	0,4	0,1	0	8,5
4,7	2,7	1,5	0,4	0,1	0	8,5	4,5	2,5	1,4	0,4	0,1	0	8,6

Enclosure F

The Organisation of SKUP

Scandinavian evaluation of laboratory equipment for primary health care, *SKUP*, is a co-operative commitment of NOKLUS [2] in Norway, "Afdeling KKA"[3] in Odense, Denmark and EQUALIS [4] 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 goal of SKUP is to produce reliable, objective and independent information about the analytical quality and user-friendliness of laboratory equipment for primary healthcare. This information is generated by organising *SKUP evaluations*.

SKUP offers manufacturers and suppliers evaluations of equipment for primary healthcare and also of devices for self-monitoring of blood glucose. As long as 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 in return, receives 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 his representative. SKUP signs *contracts* both with the requesting company and with the evaluating laboratories. A *complete evaluation* requires both one part performed by experienced laboratory personnel and one part performed by the intended users.

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

SKUP reports are published at www.skup.nu (and www.SKUP.dk) and summaries are distributed to physicians' offices, councils for laboratory medicine, laboratory instructors and healthcare authorities.

For a detailed list of previous SKUP evaluations, please look in Attachment 1.

[2] NOKLUS (Norwegian Quality Improvement of Primary Care Laboratories) is an organisation attached to "Seksjon for Allmennmedisin" (Section for General Medicine) at the University of Bergen, in Bergen, Norway.

[3] "Afdeling KKA" is the Department for Clinical Chemistry at the University Hospital in Odense, Denmark. "Afdeling KKA" in Odense and the national "Fagligt Udvalg vedrørende Almen Praksis" (Professional Committee for General Practice) have through an agreement created "the SKUP-division in Denmark". "Fagligt Udvalg vedrørende Almen Praksis"is a joint committee for "PLO", "Praktiserende Lægers Organisation" (General Practioners Organisation) and "Sygesikringens Forhandlingsudvalg" (Committee for Negotiations within the General Health Insurance System).

[4] 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 Läkarsällskapet" (Swedish Society of Medicine) and IBL (Swedish Institute of Biomedical Laboratory Science).

Enclosure G

Evaluations under the direction of SKUP

Summaries and complete reports from the evaluations are found at www.skup.nu

Evaluations performed in 2004 - 2006

Evaluation no.	Component	Instrument/testkit	Producer
SKUP/2005/52*	Strep A	Clearview Exact Strep A Dipstick	Applied Biotech, Inc.
SKUP/2005/51*	Glucose[1]	FreeStyle	Abbott Laboratories
SKUP/2006/50	Glucose[1]	Glucocard X-Meter	Arkray, Inc.
SKUP/2006/48	Glucose[1]	Accu-Chek Sensor	Roche Diagnostic
SKUP/2006/47	Hematology	Chempaq XBC	Chempaq
SKUP/2005/46*	PT-INR		
SKUP/2006/45	Glucose[1]	HemoCue Monitor	HemoCue AB
SKUP/2005/44	Glucose[1]	Accu-Chek Aviva	Roche Diagnostics
SKUP/2005/43	Glucose[1]	Accu-Chek Compact Plus	Roche Diagnostics
SKUP/2005/42*	Strep A	Twister Quick-Check Strep A	ACON laboratories, Inc.
SKUP/2005/41*	HbA1c		
SKUP/2005/40	Glucose[1]	OneTouch GlucoTouch	LifeScan, Johnson & Johnson
SKUP/2005/39	Glucose[1]	OneTouch Ultra	LifeScan, Johnson & Johnson
SKUP/2004/38*	Glucose[1]	GlucoSure Plus	Apex Biotechnology Corp.
SKUP/2004/37*	u-hCG	Quick response u-hCG	Wondsfo Biotech
SKUP/2004/36*	Strep A	Dtec Strep A testcard	UltiMed
SKUP/2004/35*	u-hCG	QuickVue u-hCG	Quidel Corporation
SKUP/2004/34*	u-hCG	RapidVue u-hCG	Quidel Corporation
SKUP/2004/33	PT-INR	Hemochron Jr. Signature	ITC International Technidyne Corp
SKUP/2004/32*	Strep A	QuickVue In-Line Strep A test	Quidel Corporation
SKUP/2004/31*	PT-INR		
SKUP/2004/30	Glucose[1]	Ascensia Contour	Bayer Healthcare
SKUP/2004/29	Haemoglobin	Hemo_Control	EKF-diagnostic

*A report code followed by an asterisk, indicates that the evaluation for instance is a pre-marketing evaluation, and thereby confidential. A pre-marketing evaluation can result in a decision by the supplier not to launch the instrument onto the Scandinavian marked. If so, the evaluation remains confidential. The asterisk can also mark evaluations at special request from the supplier or evaluations that are not complete according to SKUP guidelines, e.g. the part performed by the intended users was not included in the protocol.

[1] Including a user-evaluation among diabetic patients.

Evaluations performed in 2001 - 2003

Evaluation no.	Component	Instrument/testkit	Producer
SKUP/2003/28*	Strep A	QuickVue In-Line Strep A test	Quidel Corporation
SKUP/2003/27*	Strep A	QuickVue Dipstick Strep A test	Quidel Corporation
SKUP/2003/26*	HbA1c		
SKUP/2003/25*	HbA1c		
SKUP/2003/24*	Strep A	OSOM Strep A test	GenZyme, General Diag.
SKUP/2002/23*	Hgb, CRP	ABX Micros CRP	ABX Diagnostics
SKUP/2002/22	Glucose[1]	GlucoMen Glycó	Menarini Diagnostics
SKUP/2002/21	Glucose[1]	FreeStyle	TheraSense Inc.
SKUP/2002/20	Glucose	HemoCue 201	HemoCue AB
SKUP/2002/19*	PT-INR	Reagents and calibrators	
SKUP/2002/18	u-albumin	HemoCue	HemoCue AB
SKUP/2001/17	Haemoglobin	Biotest Hb	Biotest Medizin-technik GmbH
SKUP/2001/16*	Urin teststrip	Aution Sticks and PocketChem UA	Arkray Factory Inc.
SKUP/2001/15*	Glucose	GlucoSure	Apex Biotechnology Corp.
SKUP/2001/14	Glucose	Precision Xtra	Medisense
SKUP/2001/13	SR	Microsed SR-system	ELECTA-LAB
SKUP/2001/12	CRP	QuikRead CRP	Orion
SKUP/2000/11	PT-INR	ProTime	ITC International Technidyne Corp
SKUP/2000/10	PT-INR	AvoSure PT	Avocet Medical Inc.
SKUP/2000/9	PT-INR	Rapidpoint Coag	
SKUP/2000/8*	PT-INR	Thrombotest/Thrombotrack	Axis-Shield
SKUP/2000/7	PT-INR	CoaguChek S	Roche Diagnostics
SKUP/2000/6	Hematology	Sysmex KX-21	Sysmex Medical Electronics Co
SKUP/2000/5	Glucose	Accu-Chek Plus	Roche Diagnostics
SKUP/1999/4	HbA1c	DCA 2000	Bayer
SKUP/1999/3	HbA1c	NycoCard HbA1c	Axis-Shield PoC AS
SKUP/1999/2*	Glucose	Precision QID/Precision Plus Electrode, whole blood calibration	Medisense
SKUP/1999/1	Glucose	Precision G/Precision plus Electrode, plasma calibration	Medisense

A report code followed by an asterisk, indicates that the evaluation for instance is a pre-marketing evaluation, and thereby confidential. A pre-marketing evaluation can result in a decision by the supplier not to launch the instrument onto the Scandinavian marked. If so, the evaluation remains confidential. The asterisk can also mark evaluations at special request from the supplier or evaluations that are not complete according to SKUP guidelines, e.g. the part performed by the intended users was not included in the protocol.

[1] Including a user-evaluation among diabetic patients.

Grey aera – The instrument is not in the market anymore.

Enclosure H

chempaq

Farum, 18th May, 2006

Comments to SKUP Report

Chempaq XBC is an inexpensive, dedicated point-of-care system. It is intended and designed for decentralized testing. The Chempaq XBC has been compared to a more expensive and more complex system (Sysmex SE-9000) for professional use. During the comparison the following features have been positively verified:

a) Chempaq XBC is with very few exceptions, easy to use (ref. chapter 5.12 in the report).
b) The Chempaq XBC precision for Hb and WBC is in the same order of magnitude as the Sysmex SE-9000. Furthermore, the Chempaq XBC system fulfils the precision demands in Denmark for both venous and capillary blood samples in the hospital evaluation and for venous samples in the de-centralized evaluations (ref. chapters 5.3.1, 5.3.2, 5.5.1 and 5.6). The inability of the de-centralized units to obtain, as compared to the hospital unit, comparable precision for capillary samples can be attributed to well-known pre-analytical errors associated with capillary sampling.
c) The Chempaq XBC bias (accuracy), as compared to Sysmex SE-9000, for Hb and WBC fulfils the accuracy demands in Denmark for both in venous and capillary blood samples of the hospital evaluation and to a large extent for the de-centralized evaluations (ref. chapters 5.3, 5.4, 5.5 and 5.6). The Sysmex SE-9000 WBC data have been mathematically corrected after analysis due to an observed bias to material of reference.
d) Chempaq XBC has the ability to flag potentially abnormal samples from a variety of patients (ref. chapter 5.7).

During the study it was experienced that certain lots had an elevated error frequency (enclosure A & B). Corrective actions have been completed and since March 2006, error frequency has been reduced to less than 1%, as experienced during the hospital evaluation.

During the initial part of the de-centralized evaluation the performance was impaired due to faults in particular lots of the Chempaq XBC disposable units used. After corrective actions the performance was improved.

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