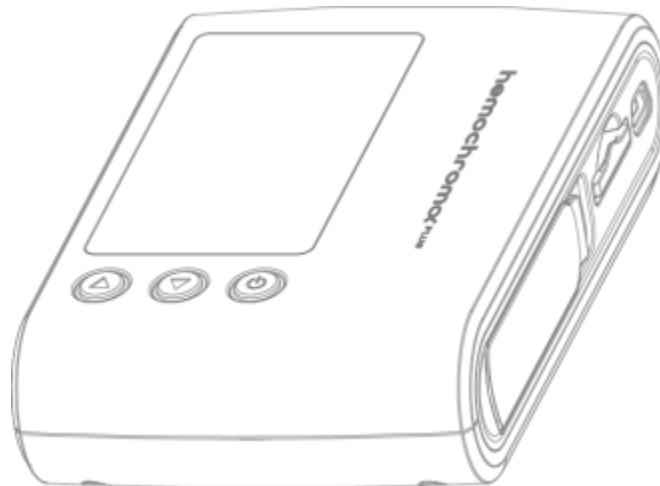


Technical Data package
Rev.01

PERFORMANCE DATA OF **hemochromα** PLUS



BIO TECHNOLOGY
boditech
BODITECH MED INC.

Introduction

Hemoglobin Meter

Dual wavelength
Hemoglobin meter
based on
Micro cuvette



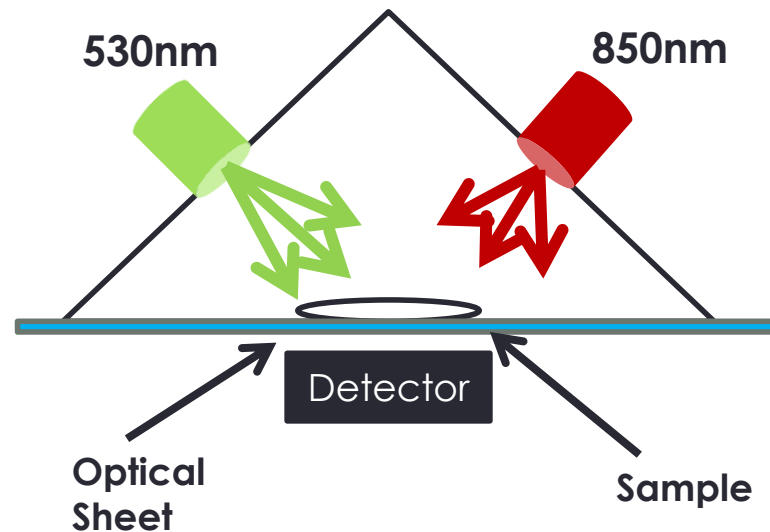
Specification

항목	Hemochroma PLUS	Remark
측정항목 (Marker)	Hemoglobin concentration in whole blood	전혈의 헤모글로빈 검사
측정범위 (Range)	0 ~ 27 g/ dL (actual 5.0~17 g/dL)	Published spec. 0~27 g/dL
측정방법 (Methodology)	Dual Length Absorbance in micro-cuvette Non-hemolysis, whole blood	전혈 흡수도 측정법
재현성 (CV%)	Inter-batch <=1% Reader-to-reader <=4%	
상관성 (Correlation)	R square >=0.96 (Sysmax, tube blood)	Tube blood 기준
시료량 (Sample volume)	12 ~ 15uL	Finger 12uL, Tube 15 uL
측정시간 (Time)	10 sec	
편의성 (Convenience)	Auto cartridge holder	노후시 홀더 닫힘 불량시 수동 처리
저장용량 (Storage)	1000 개 저장	
크기 (Dimension)	106.5x 151 x 38.5 mm	
중량 (Weight)	230g	
구동전압 (Voltage)	Battery operated 12 hours working Sleep mode function: within 5 mins.	1회 건전지 삽입후 연속동작 12시간 (USB 전원 사용가능-QC용)
출력 (Output)	USB for PC Printer with RS232 (only for printing) Bluetooth communication	PC interface 프로그램 사용가능 – USB RS232 → data 출력만 가능 프린터 전용 Bluetooth 통신 옵션

Principal of device

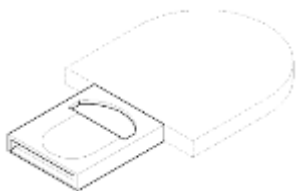
LED based optical system

Dual wavelength
Auto calibration
Direct absorbance
Whole blood

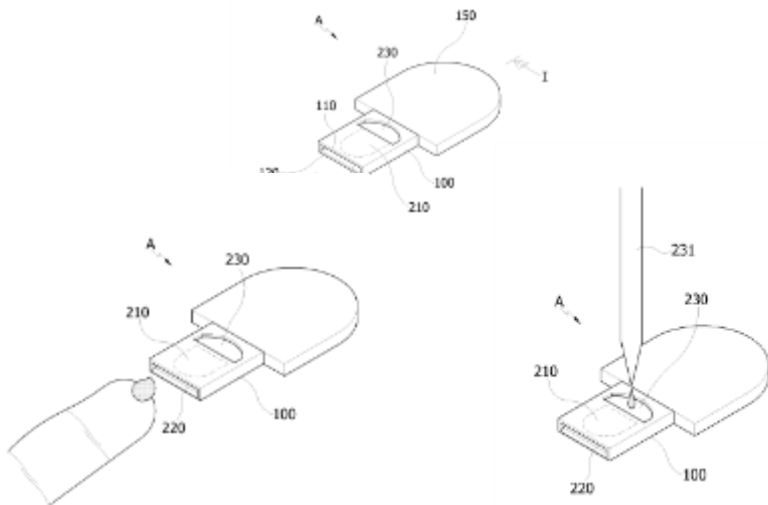


Patent pending

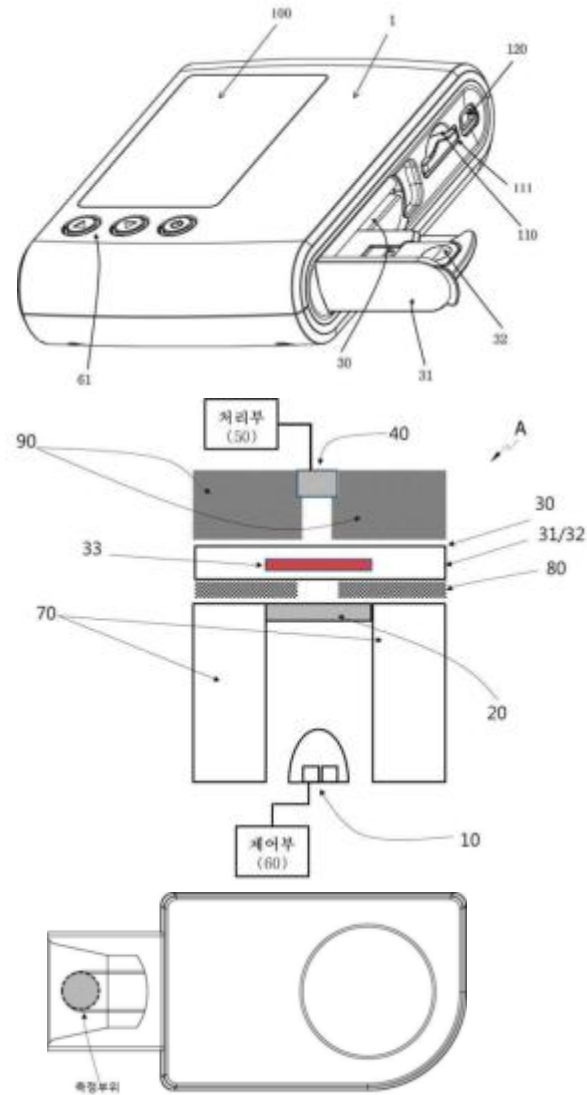
물품의 명칭 : 마이크로 큐베트
 출원일: 2011년 8월 16일
 출원번호: 제 30-2011-0034087 호



발명의 명칭 : 이중 채취수단을 갖는 모세관 마이크로 큐베트
 출원일: 2011년 8월 16일
 출원번호: 제 10-2011-0080964 호



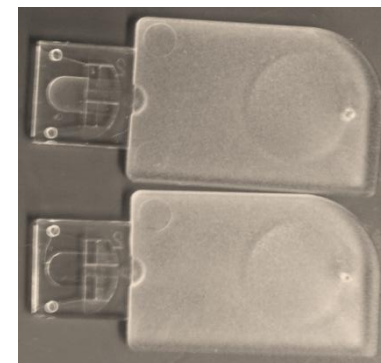
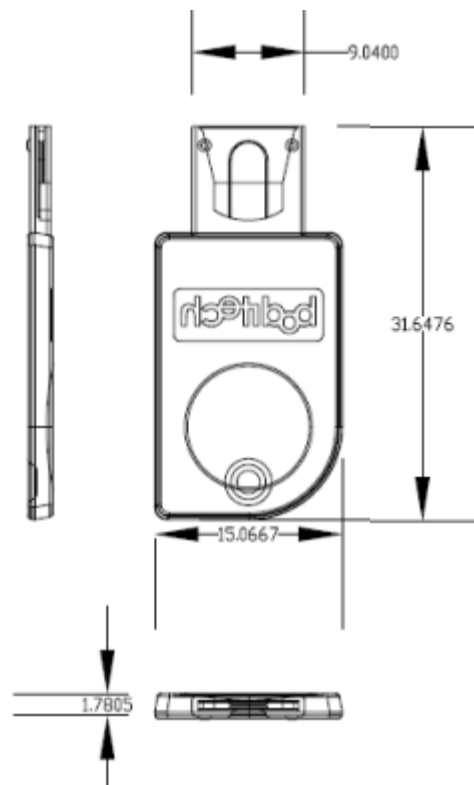
발명의 명칭 : 헤모글로빈 측정장치 및 방법
 출원일자 : 2012-04-13
 출원번호 : 10-2012-0038223



Micro cuvette

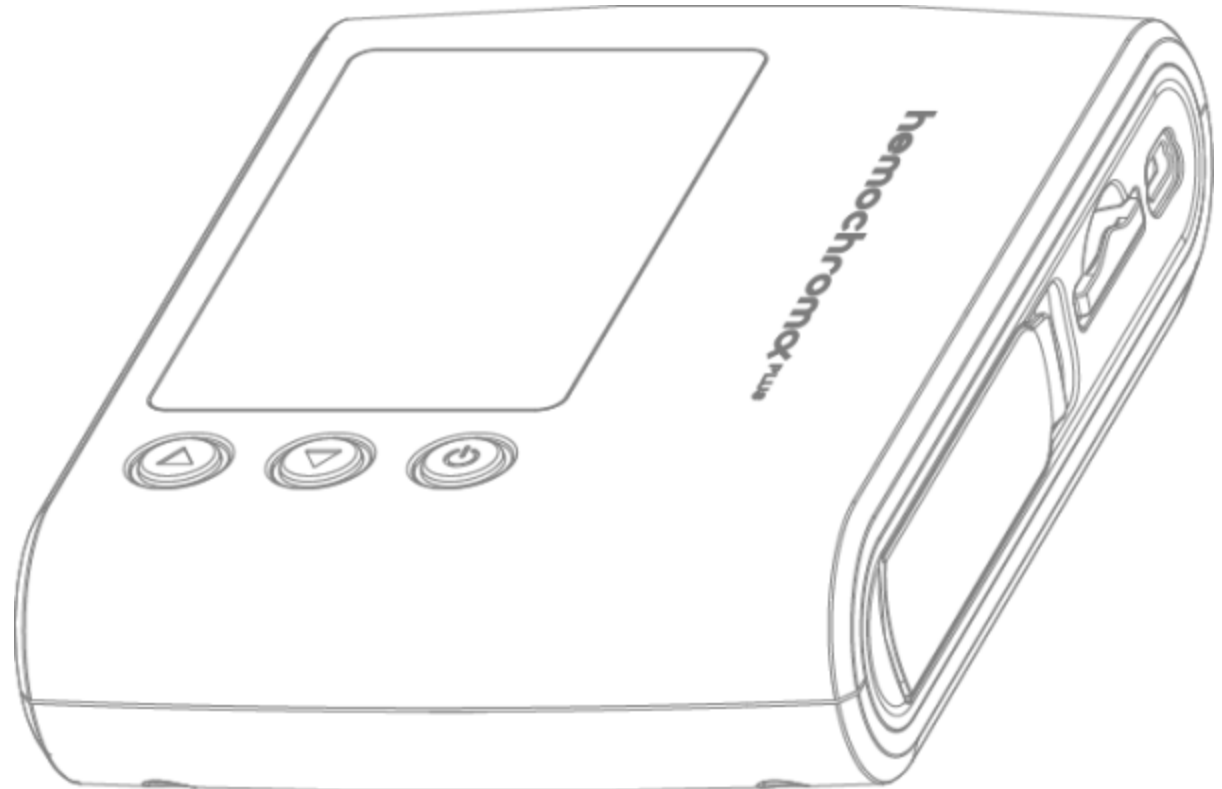
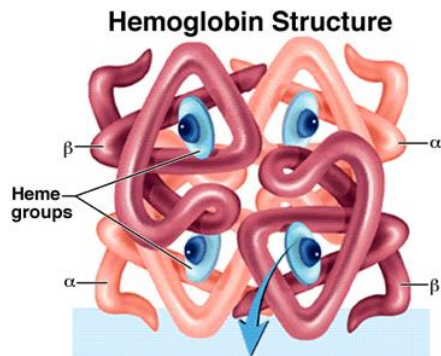
Cell gap: 100-200 μm

Volume: 12 – 15 μL



Performance data of reader

Correlation
Reproducibility
Comparison



Correlation test with Sysmex® in venous blood

- **Purpose**

- Evaluation for correlation with Sysmex (KX21N)

- **Methods**

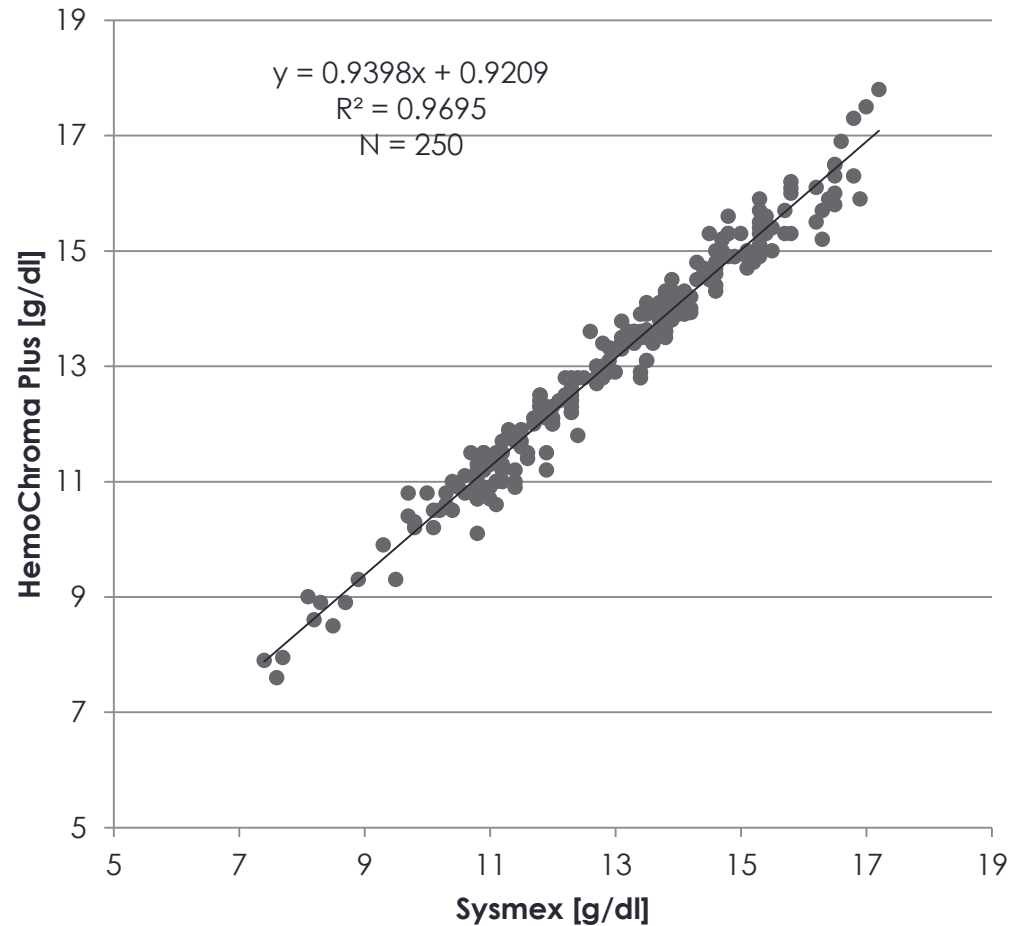
- 208 of venous blood (within 7 days after collection)
- Test with 6 Hemochroma PLUS reader

- **Result**

- R2 = 0.969
- Slope = 0.939

- **Conclusion**

- Hemochroma PLUS shows high correlation coefficient value with Sysmex.



Correlation with Sysmex® in internal control

- **Purpose**

- Evaluation for reader-to-reader correlation with internal control

- **Methods**

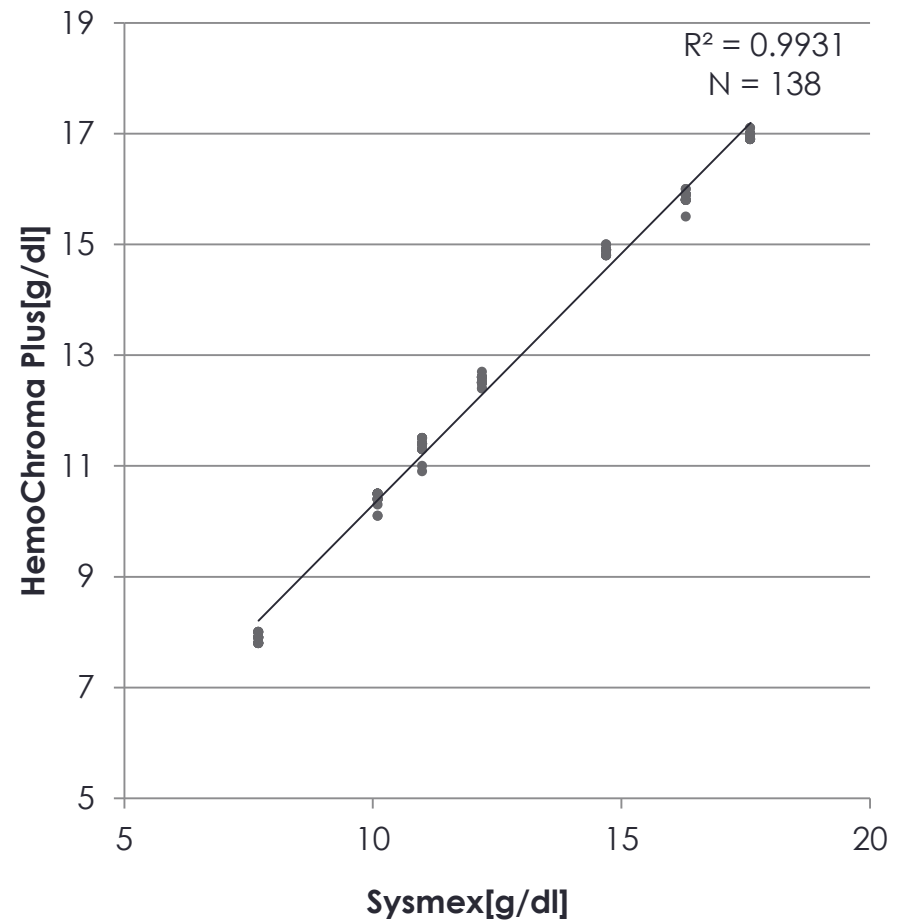
- Internal control is in-house control that was from hemolyzed bovine blood
- Hb concentration of Internal control was tested and validated with Sysmex.
- Randomly selected reader was tested with validated internal control for 138 times

- **Results**

- $R^2 = 0.9931$

- **Conclusion**

- Hemochroma PLUS showed high correlation with Sysmex value.



Reproducibility of reader –to-reader

- **Purpose**

- Evaluation of CV% between reader

- **Methods**

- Samples: Venous blood (No. of samples 67)
- Tested Hemochroma PLUS readers(No. of readers 43)
- Total repeated 2,881 (43 readers x 67 samples) data were analyzed

- **Results**

- In reader-to-reader CV%, it showed maximum 3.8% CV between readers

- **Conclusion**

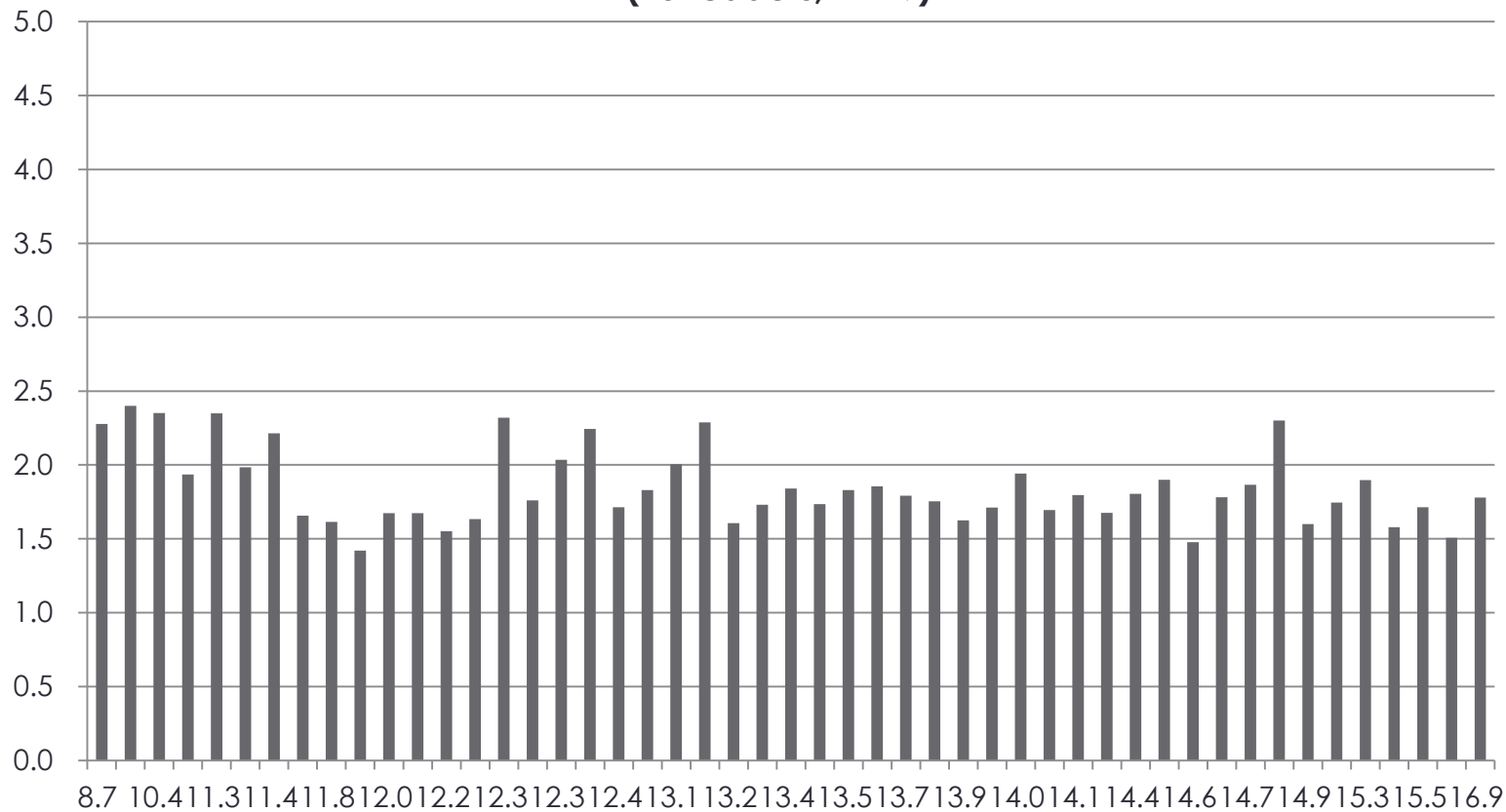
- Random selected 50 of readers showed CV% 1.36 ~ 3.81.

Test results for reproducibility of reader-to-reader

Criteria	Test 1	Test 2	Total
No. of readers tested	25	18	43
No. of samples	49	18	67
MAX CV%	2.40	3.81	3.81
MIN CV%	1.42	1.36	1.36

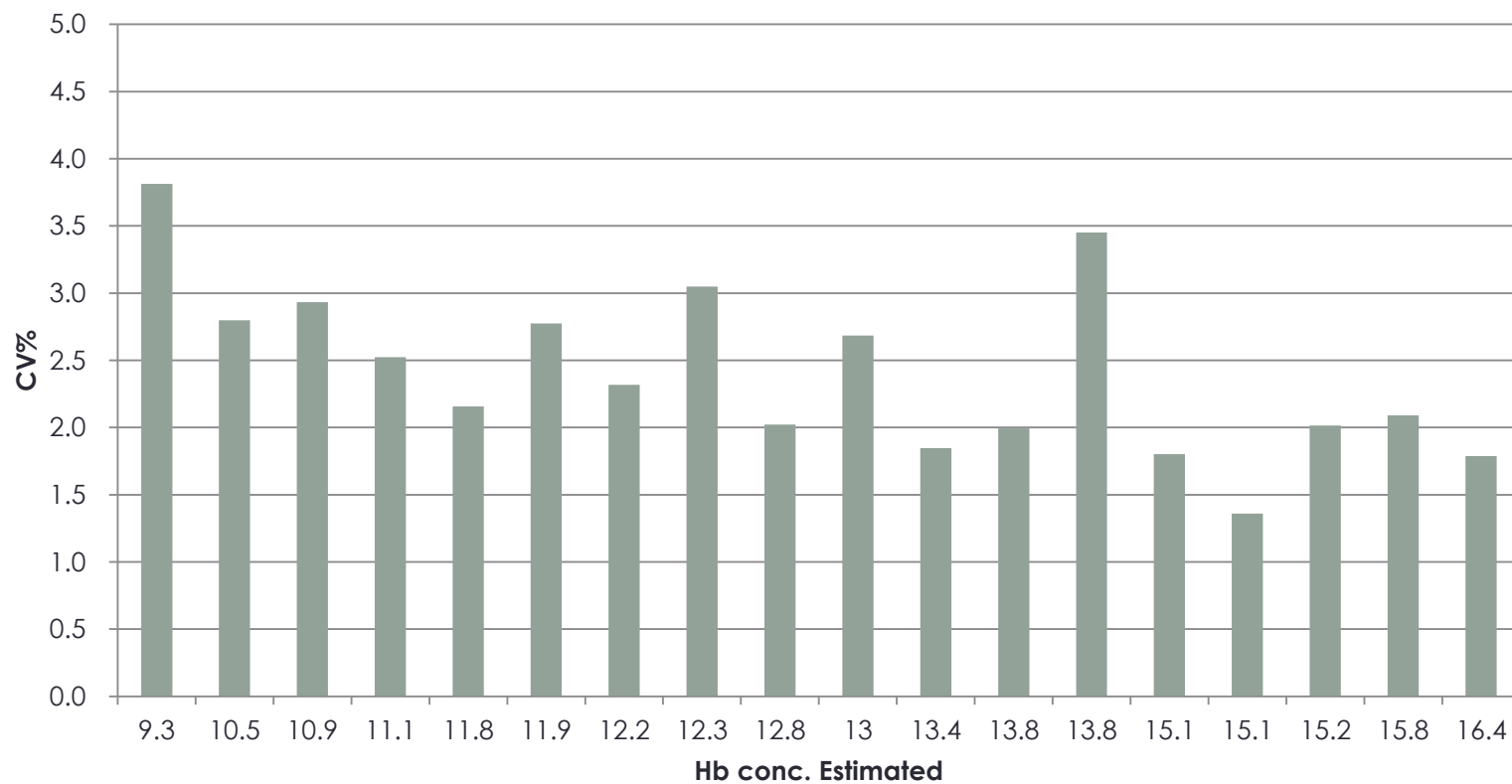
Test 1: 49 samples

**CV% of reader-to-reader
(25 readers, N=49)**



Test 2: 18 samples

**CV% of reader-to-reader
(18 reader, N=18)**



Test repeatability in reader

- **Purpose**

- Evaluation of test repeatability in readers

- **Methods**

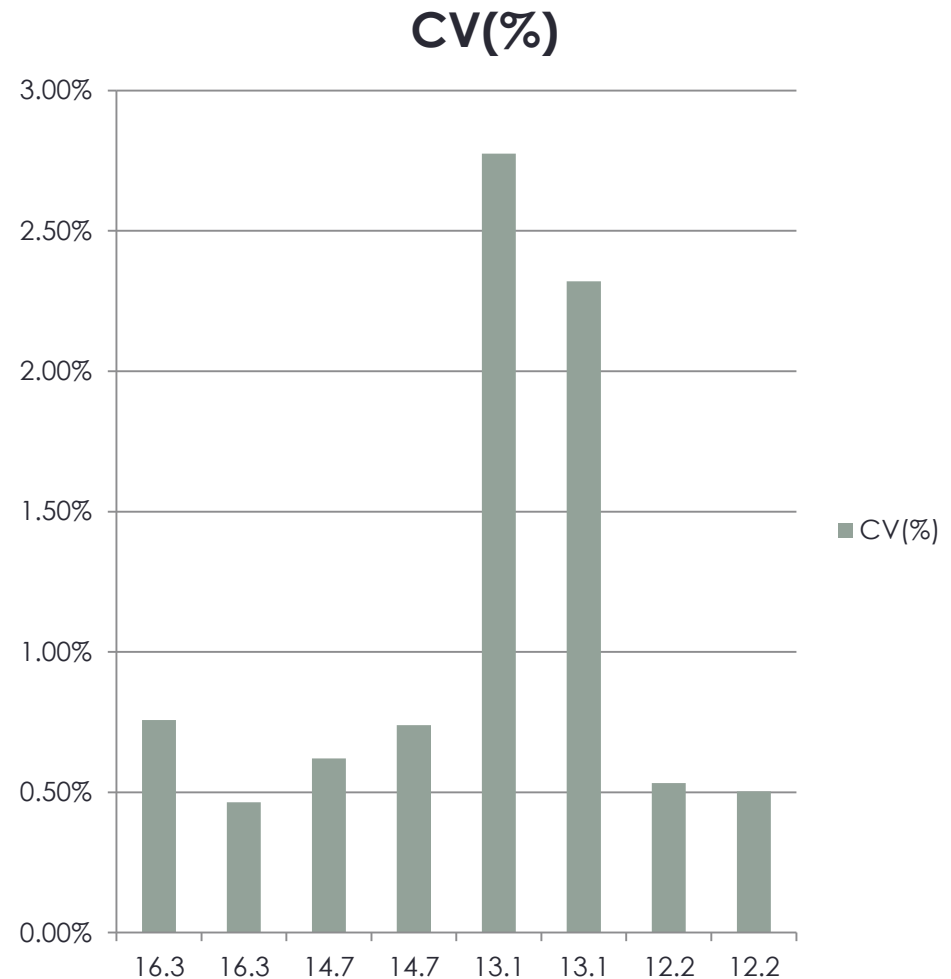
- Normal range of internal standards 12.2, 13.1, 16.3 g/dL were used.
- Normal range of internal standard control (n=8) was tested 10 times repeatedly in 2 readers

- **Results**

- Test repeatability is showed 0.46 ~ 2.77 CV%
- In samples of 13 g/dL showed highest CV%

- **Conclusion**

- Test repeatability was mostly less than CV 1 %.
- Max CV was 2.77%



Comparison with Hemocue® 301

- **Purpose**

- Comparison study with Hemocue 301

- **Methods**

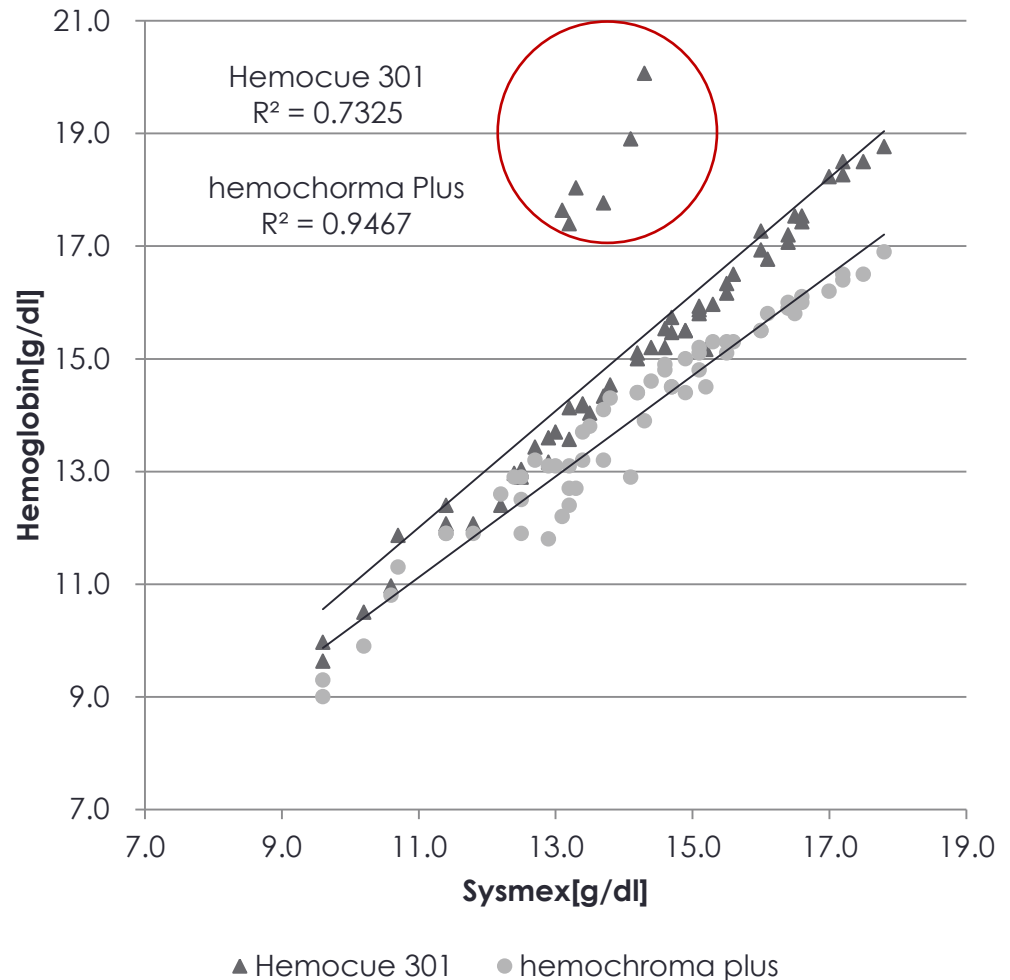
- 60 whole blood samples were tested with Hemochroma PLUS and Hemocue 301

- **Results**

- Hemochroma PLUS $R^2 = 0.95$
- Hemocue 301 $R^2 = 0.73$

- **Conclusion**

- 6 samples showed different results in Hemocue 301.
- It cause from blood status, hemochroma PLUS is more higher correlation in stored blood.



Performance Micro Cuvette

Repeatability
Reproducibility
Batch variation



Repeatability of cuvette

- **Purpose**

- Evaluation of test CV% of same cuvette batch

- **Methods**

- Samples: Internal standard, Hb 12.1g/dL was used.
- 10 cuvette were tested each 6 batches
- Estimate test CV%

- **Results**

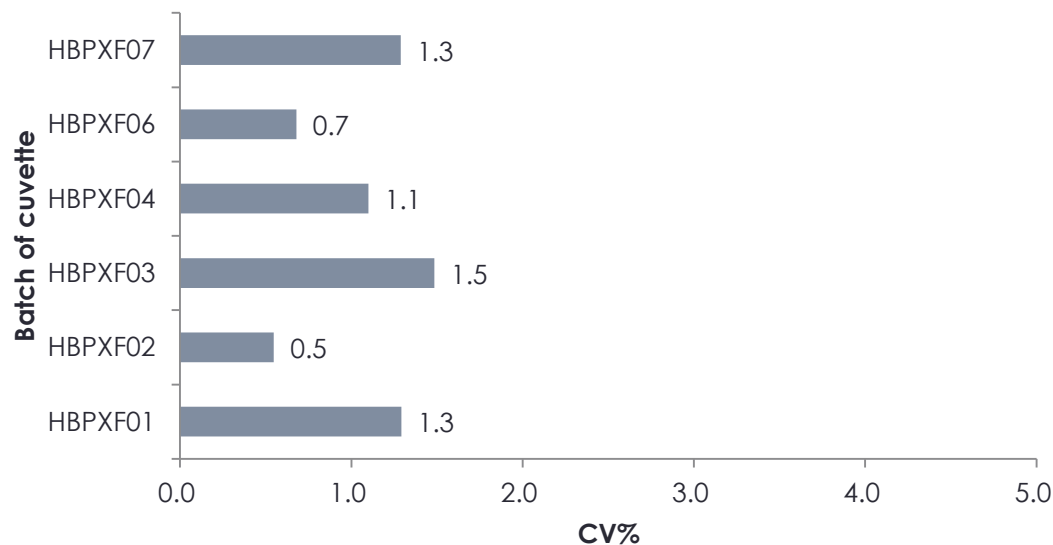
- Estimated CV%: 0.5 ~ 1.3

- **Conclusion**

- Test variation of cuvette was estimated within CV 1.3%.

Batch	Run1	Run2	Run3	Run4	Run5	Run6	Run7	Run8	Run9	Run10	AVG	CV(%)
HBPXF01	12.0	12.1	12.0	12.0	12.2	12.0	12.0	12.5	12.1	12.1	12.1	1.3
HBPXF02	12.3	12.4	12.4	12.3	12.2	12.3	12.3	12.4	12.3	12.4	12.3	0.5
HBPXF03	12.8	12.4	12.8	12.3	12.7	12.8	12.8	12.8	12.8	12.8	12.7	1.5
HBPXF04	12.7	12.7	12.7	12.6	12.7	12.7	13.1	12.7	12.7	12.6	12.7	1.1
HBPXF06	12.1	12.1	12.1	12.0	12.2	12.2	12.3	12.1	12.1	12.1	12.1	0.7
HBPXF07	12.1	12.0	12.0	12.1	12.2	12.4	12.4	12.0	12.2	12.3	12.2	1.3

Repeatability of Cuvette (CV%)



Reproducibility of cuvette batches

- **Purpose**

- Evaluation of reproducibility of each cuvette batches

- **Methods**

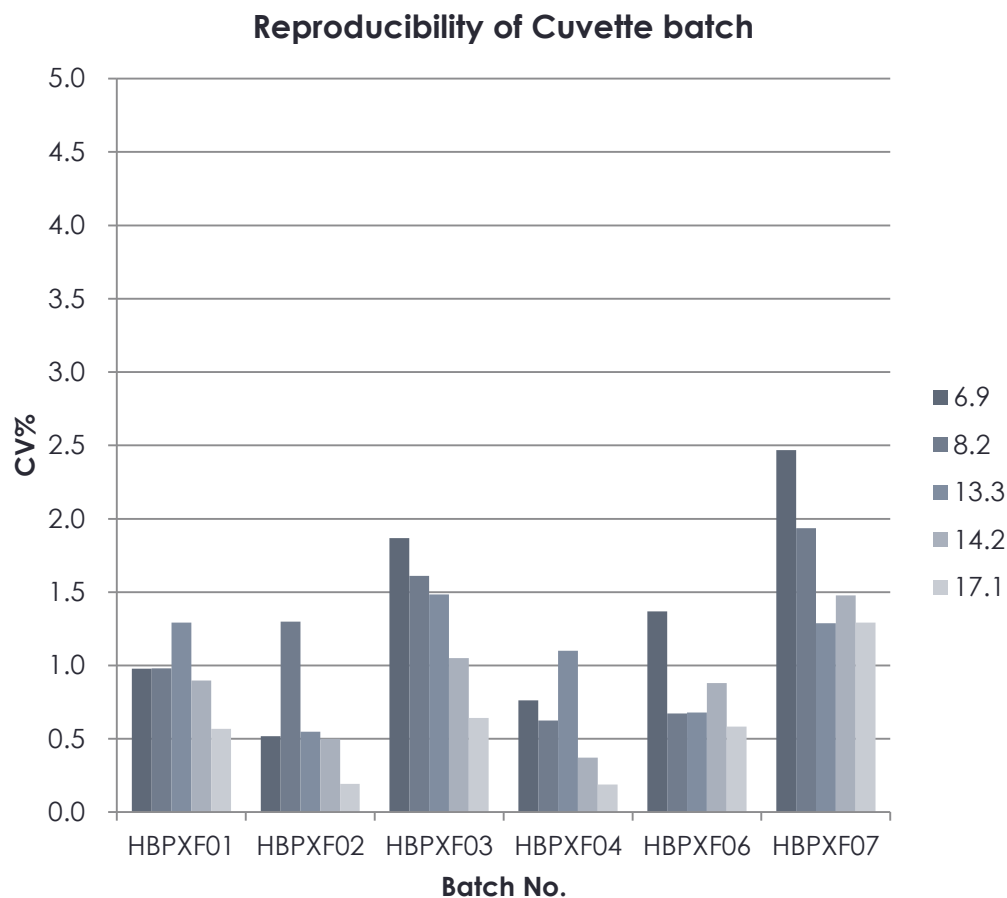
- Samples: Internal standard panel .
- 10 cuvette were tested each 6 batches
- Estimate test CV%

- **Results**

- Estimated CV%: 0.2 ~ 2.5

- **Conclusion**

- High reproducibility between cuvette batches.



Correlation coefficient between cuvette batches

- **Purpose**

- Evaluation of correlation of each cuvette batches

- **Methods**

- Samples: Internal standard panel .
- 10 cuvette were tested and calculate average,
- Estimate the correlation coefficient value (R^2)

- **Results**

- Correlation coefficient: above than 0.99 in every batch with Sysmax value

- **Conclusion**

- High correlation between cuvette batches.

