

# CLOVER<sup>+</sup> A1c<sup>TM</sup> Self

HbA1c Monitoring System

Fully  
Automatic

4 $\mu$ l

5 min

- Fully Automatic
- Boronate Affinity
- Spectrophotometry
- 4 $\mu$ l Blood Sample
- Test Result in 5 Minutes



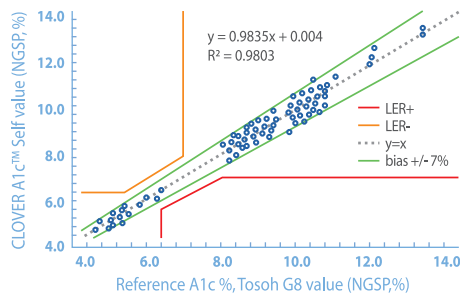
**Labcare**  
de Colombia  
[www.labcarecolombia.com](http://www.labcarecolombia.com)

# CLOVER<sup>®</sup> A1c<sup>™</sup> Self

## Accuracy

### 1. Comparison method

CLOVER A1c<sup>™</sup> Self analyzer vs Tosoh G8, N=120

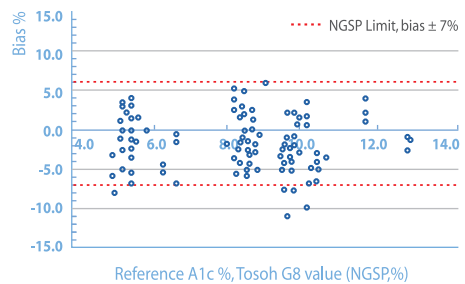


Sample type	Regression line	slope	y-interceptor	R2
capillary blood	y=0.9835x-0.004	0.9835	-0.004	0.9803

Table1. Summary of regression line

### 2. System bias plot (Total)

Bias plot (N=120, Limit: within bias  $\pm 7\%$ )



Within $\pm 5\%$	Within $\pm 7\%$	Within $\pm 10\%$
99/120(82.5%)	114/120(95.0%)	119/120(99.2%)

Table2. System accuracy results of capillary for HbA1c levels (mean bias, %)

## Specification

Sample type	Capillary whole blood, Venous blood with anticoagulant
Sample volume	4 $\mu$ l
Test range	4.0~14.0%
Reading time	5 minutes
Memory capacity	200 test results
Wavelength	415 nm (normal)
Power required	DC 9V-1.5 A
Dimensions / Weight	200 x 200 x 139(mm) / 1.4kg
Storage temperature	10~35°C (50~95°F)
Operating temperature	17~32°C (63~90°F)
Relative humidity range	10%~90%

## Precision

### 1. Acceptance criteria of CV

Total imprecision (CV) must not be statistically significantly 3%

### 2. Test result

	Normal	Abnormal
Mean, (%)	5.3	10.0
SD	0.14	0.19
CV, (%)	2.7	1.9

Table1. Mean values, Standard deviation (SD), coefficient variation (CV) of each sample

### 3. Conclusion

All CV at each HbA1c level are in the acceptance criteria.

## Test Procedure



Open the CLOVER A1c Analyzer.



Insert the Cartridge.



Shake the Reagent Pack 5~6 times



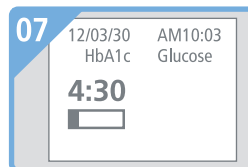
Place the blood sample (4  $\mu$ l) at the sample Collecting Area.



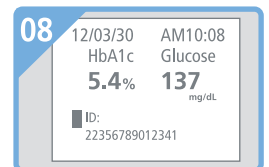
Insert the Reagent Pack into the Cartridge in the Analyzer.



Close the cover of Analyzer.



The test starts automatically by closing the cover, and the test result time countdown is displayed.



After 5 minutes, when the test is over, the HbA1c% is displayed.

## Full Package

CloverA1c<sup>™</sup> Self analyzer, Instruction for Use, Exclusive power adapter, Fan Filters, Daily check cartridge, Monthly check cartridge

\*\*Options : Blood Glucose Module, PC connection cable, Barcode Scanner, Thermal Printer