CLOVER A1c™ Self

HbA1c Monitoring System

Fully Automatic

4 μℓ

5 min

- Fully Automatic
- Boronate Affinity
- Spectrophotometry
- 4 μℓ Blood Sample
- Test Result in 5 Minutes

CLOVER ✣ A1c™ Self

Accuracy

1. Comparison method

CLOVER A1c™ Self analyzer vs Tosoh G8, N=120

$y = 0.9835x + 0.004$
$R^2 = 0.9803$

- LER+
- LER−
- ···· y=x
- bias +/- 7%
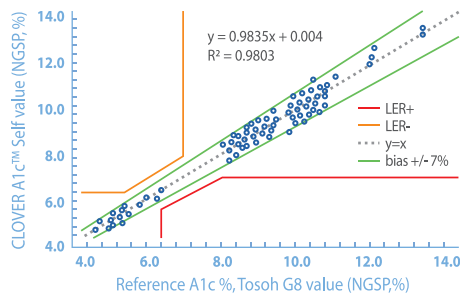
Sample type	Regression line	slope	y-interceptor	R2
capillary blood	y=0.9835x -0.004	0.9835	-0.004	0.9803

Table1. Summary of regression line

2. System bias plot (Total)

Bias plot (N=120, Limit: within bias ±7%)

···· NGSP Limit, bias ± 7%

Reference A1c %, Tosoh G8 value (NGSP,%)
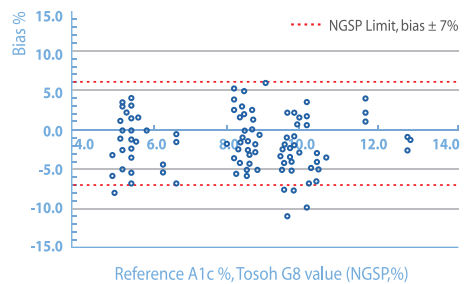
Within ±5%	Within ±7%	Within ±10%
99/120(82.5%)	114/120(95.0%)	119/120(99.2%)

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

Specification

Sampel type	Capillary whole blood, Venous blood with anticoagulant
Sample volume	4 $\mu\ell$
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 × 198 × 139(mm) / 1.4kg
Storage temperature	10~35℃ (50~95℉)
Operating temperature	17~32℃ (63~90℉)
Relative humidity range	10%~90%

Precision

1. Acceptance criteria of CV

Total imprecision (CV) must not be statistically significantly 4%

2. Test result

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

Table3. Mean values, Standard deviation (SD), coefficient variation (CV) of each sample

3. Conclusion

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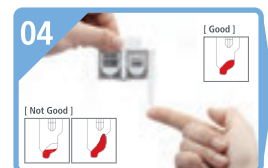
Test Procedure

01 Open the CLOVER A1c™ Self Analyzer.

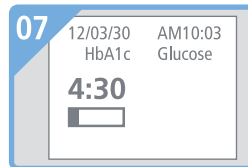**02** Insert the Cartridge.

03 Shake the Reagent Pack 5~6 times

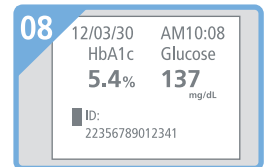**04** Place the blood sample (4 $\mu\ell$) at the sample Collecting Area.

[Good]

[Not Good]

05 Insert the Reagent Pack into the Cartridge in the Analyzer.

06 Close the cover of Analyzer.

07 12/03/30 AM10:03 HbA1c Glucose 4:30

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

08 12/03/30 AM10:08 HbA1c Glucose 5.4% 137 mg/dL ID: 22356789012341

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

Full Package

CloverA1c™ 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