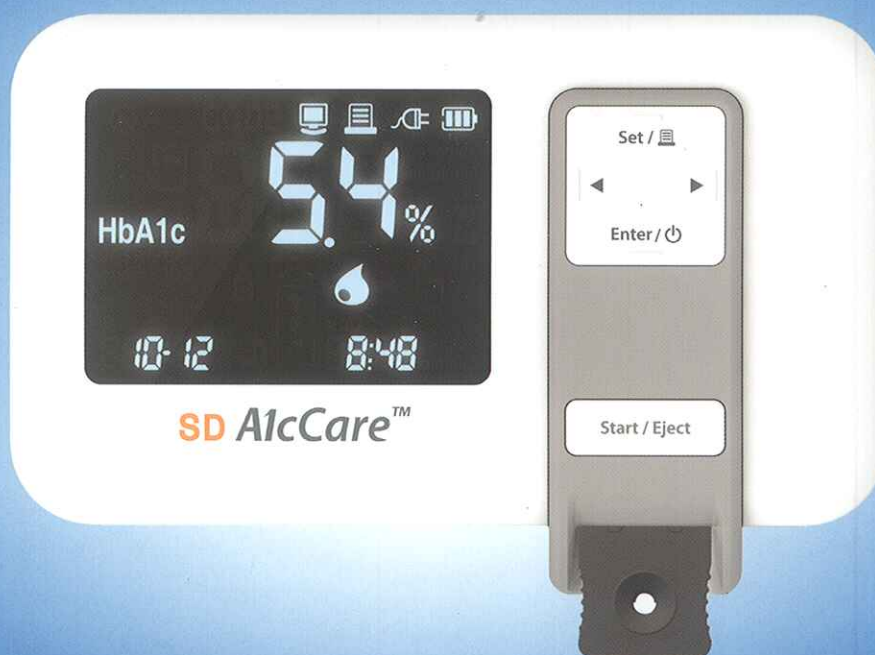


The Brilliant HbA1c System

- ✓ High accuracy & precision
- ✓ No refrigeration
- ✓ Long shelf-life
- ✓ HbA1c control material easy to use



SD A1cCare™

AIM Technology

Standard Diagnostics, Inc (SD) has developed a number of rapid qualitative tests, and achieved its reputation by manufacturing one of the world's best quality rapid point-of-care tests based on the immuno-chromatographic assay.

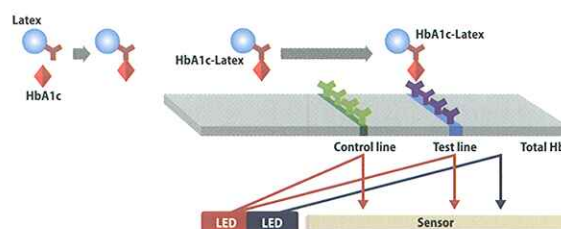
Following this success, SD BIOSENSOR has developed the most accurate quantitative immuno-chromatographic testing systems using a photo-reflectance method. Finally, SD BIOSENSOR succeeded in the development of **Advanced Immunoassay Technology**.

SD A1cCare is the first POCT system based on **AIM Technology** by SD BIOSENSOR. As known as HbA1c testing system requires the most accurate results among POCT systems, SD BIOSENSOR is excited by the possibilities to develop POCT systems for various parameters of human chronic disease based on **AIM Tech.** in near future.

Reaction Principle

By mixing the blood sample and hemolysis buffer in the buffer tube, Lysis of red blood cells exposes glycated hemoglobin (HbA1c). At the same time, latex conjugate binds to HbA1c.

While mixed reagent flows through the nitrocellulose membrane, HbA1c - latex molecules specifically bind to HbA1c antibodies on the test line. A photometric sensor measures the LED light reflected, and then %HbA1c is calculated.



Specifications

Method	Advanced Immunoassay
Measurement	%Hemoglobin A1c
Testing Time	3 minutes
Sample Volume	5 μ l
Sample Type	Whole Blood (Capillary & Venous)
Measurement Range	4 ~ 15% (20 ~ 140 mmol/mol)
Hemoglobin Range	7 ~ 23 g/dL
HCT	25 ~ 65%
Standardization of test results	NGSP, IFCC, JDS, Mono-s
Correlation(R)	≥ 0.98
Precision	CV < 3% (all ranges)
Shelf-life	18 months from manufacture
Operating Temperature	15 ~ 32°C (59 ~ 90°F)
Storage Temperature	1 ~ 30°C (34 ~ 86°F)
Memory	1,000 tests
Size / Weight	163 x 96 x 56(mm) / 450g
Accessories	Printer, Barcode Scanner, Safety Lancet



The Brilliant HbA1c System

SD A1cCare™

A1cCare is an optimized system applicable at the point-of-care testing field.

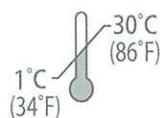


Advantages of SD A1cCare



- Performance

- Accuracy: $R^2 \geq 0.98$
- Precision: CV < 3%



- Storage condition

- RT: 1 ~ 30°C (34 ~ 86°F)
- Shelf-life: 18 months



LV1
LV2

- A1c Control material

- For single use
- Storage at RT for 18 months



- Convenience

- Small size
- Battery or mains power

Accessories

Thermal Printer

Quick to print out test results with labels.

Barcode Scanner

Easy to scan a patient ID barcode.

SD HMS(HbA1c Management Software)

Convenient to manage test results by PC Software.

SD Safety Lancet

Safe and hygienic for blood sample collection.



SD A1cCare Performance

You can trust SD A1cCare™ for enhanced precision and accuracy.

SD A1cCare™ was tested in accordance with the Clinical and Laboratory Standards Institute (CLSI), and the results showed a CV (coefficient of variation) of less than 3%.

*NGSP

*The purpose of NGSP is to provide internationally reliable and standardized HbA1c test results. Results may vary due to different laboratories, test methods and various quality controls. The NGSP aims to overcome such limitations of diabetes management and outcome analysis for patients with diabetes.

*IFCC

*The International Federation of Clinical Chemistry Working Group (IFCC-WG) on HbA1c Standardization has developed reference methods for HbA1c analysis. They have established a laboratory network, which includes two reference methods, mass spectroscopy and capillary electrophoresis.

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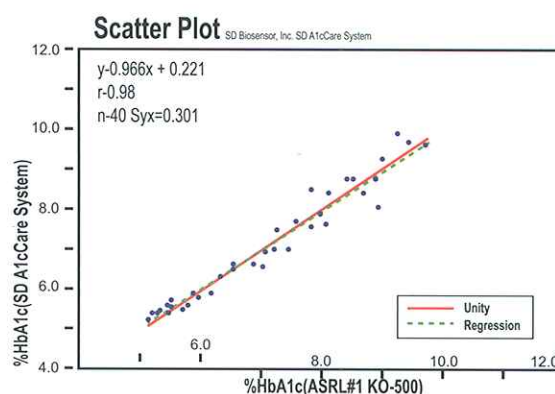
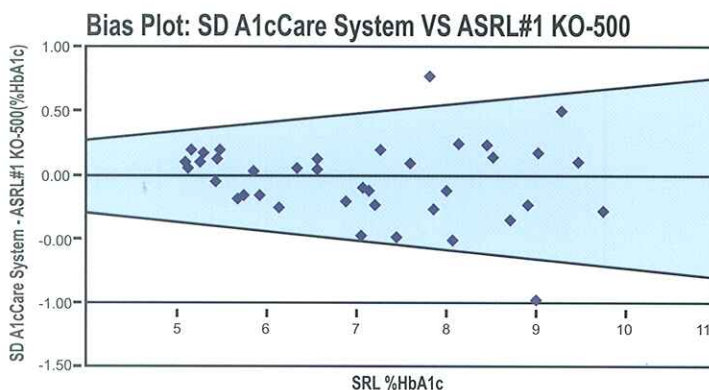


Evaluation Report (NGSP)

Samples in the HbA1c ranges outlined in the NGSP method comparison procedures:

Method comparison and Bias Estimation

For the method comparison, 40 samples are analyzed by the manufacturer and by the SRL; one set of fresh samples may be split and used to evaluate several applications or methods, thus necessitating only one evaluation of 40 samples by the SRL.



Since method's results were within the following NGSP criteria for Manufacturer Certification, SD BIOSENSOR has successfully completed the NGSP Manufacturer certification.

- **Criteria for NGSP Manufacturer certification:** **37/40** HbA1c results (single results) must be within $\pm 7\%$ of the NGSP SRL mean (mean of duplicate results).
- **Result of SD A1cCare:** **38/40** HbA1c results (single results) were within $\pm 7\%$ of the NGSP SRL mean (mean of duplicate results).



System Contents

SD A1cCare System Packages

Analyzer



Test Kit (B type)



HbA1c Control



SD A1cCare System Contents

Analyzer

- A1cCare Analyzer
- Check Strip
- DC Adapter
- User Manual
- Quick Guide



Test Kit (B type)

- Test Set x 20
- Buffer Tube x 20
- Code-chip
- Test Kit Insert



HbA1c Control

- HbA1c Control Level 1 x 10
- HbA1c Control Level 2 x 10

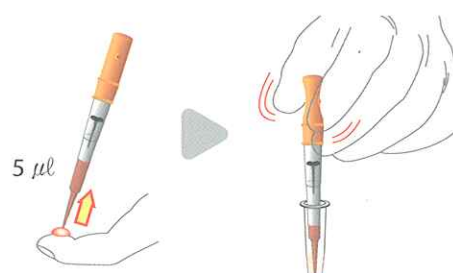


Test Procedure

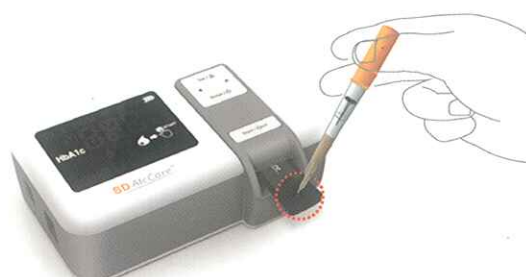
1 Insert a test panel.



2 Take 5 μ l of blood sample and mix it with buffer solution.



3 Apply mixed sample to the test panel.



4 Check the result after 3 minutes.



※ Search "A1cCare" on Youtube.