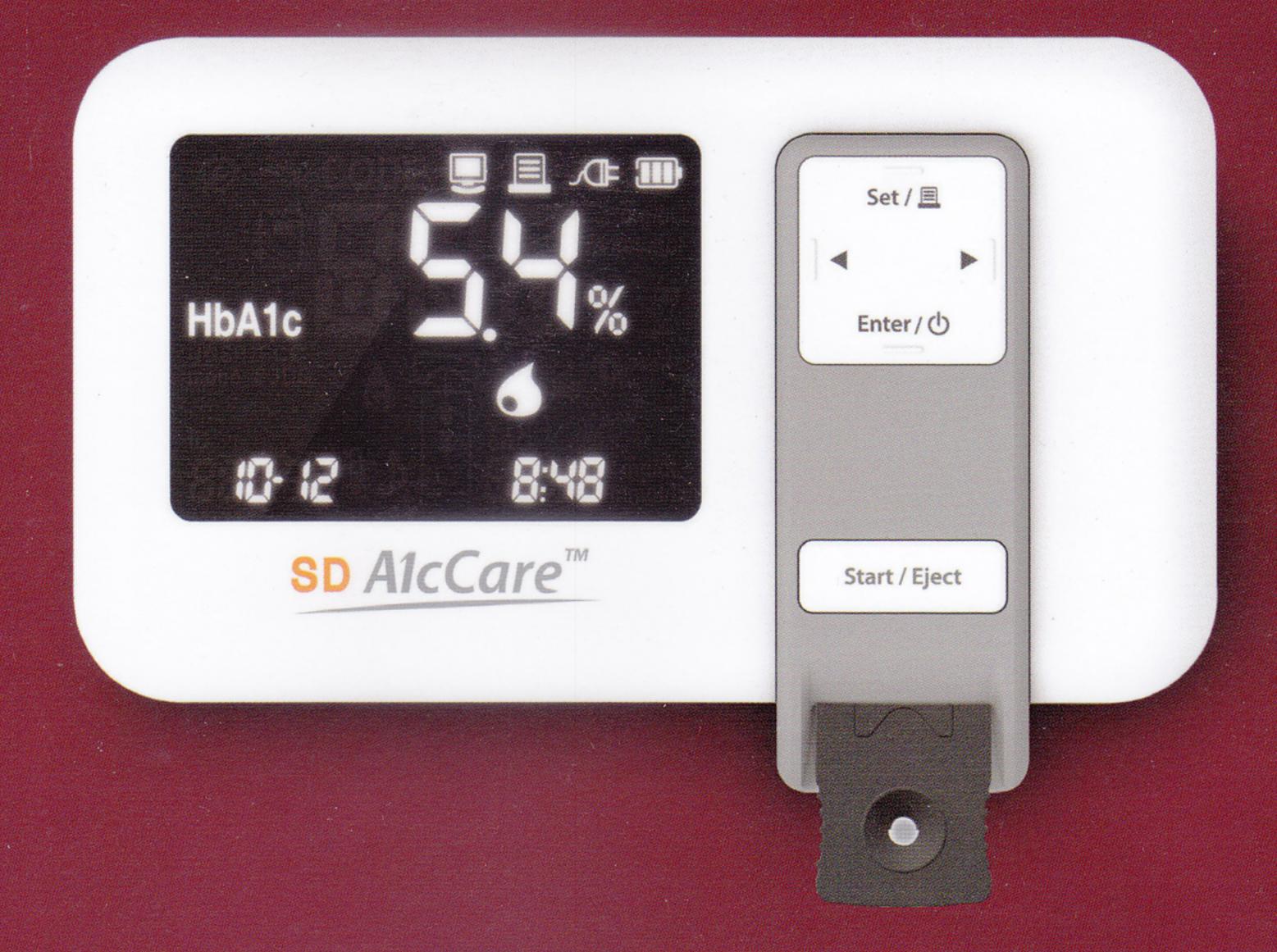


# The Brilliant HbA1c System

Accurate & Simple



SD A1cCare TM



#### SD A1cCare Performence

#### You can trust SD A1cCare<sup>™</sup> for enhanced precision and accuracy.

SD A1cCare™ was tested in accordance with the Clinical and Laboratory Standards Institute(CLSI), and has successfully achieved NGSP and IFCC certifications with very reliable accuracy and precision.



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



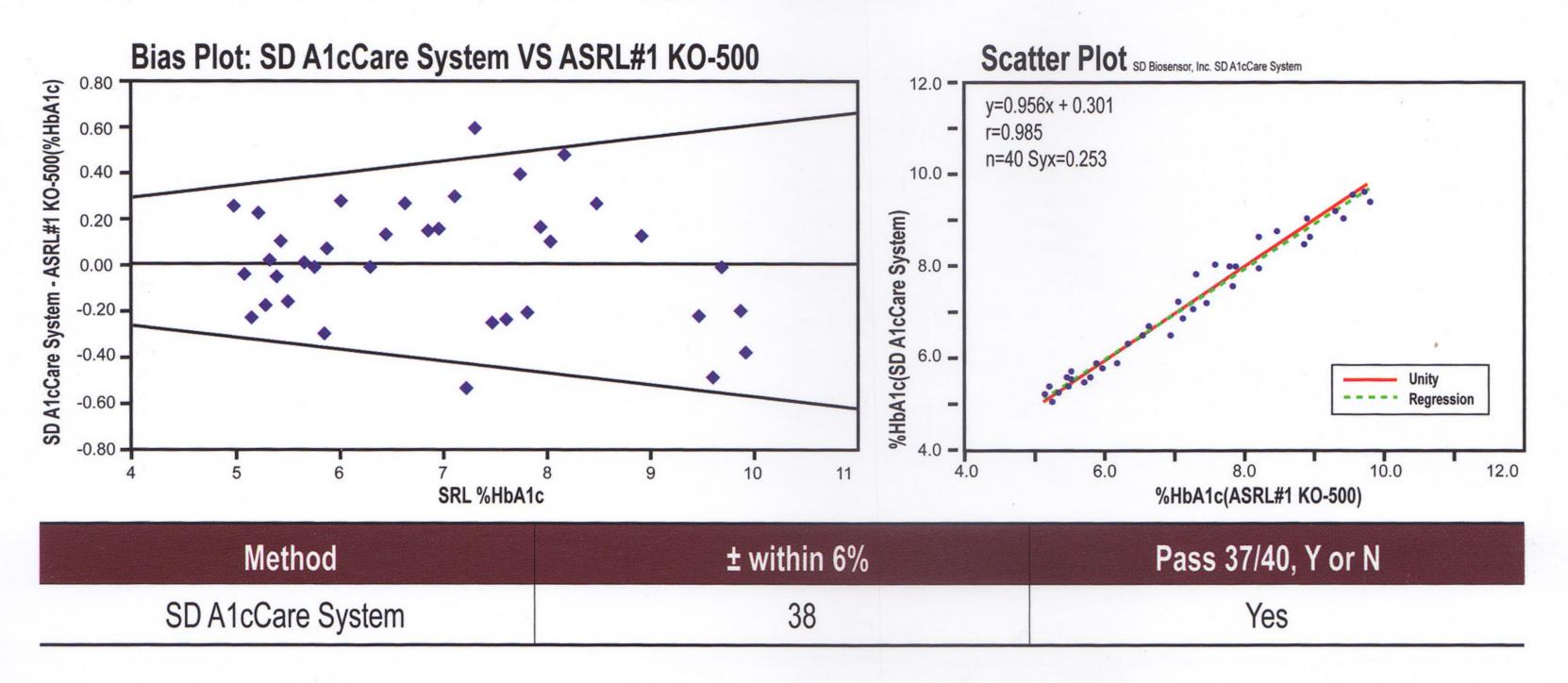
The International Federation of Clinical Chemistry Working Group (IFCC-WG) on HbA1c Standardization has developed reference methods for HbA1c analysis. They have established a laboratory network, which includes two reference methods, mass spectroscopy and capillary electrophoresis.

#### Evaluation Report (NGSP)

and outcome analysis for patients with diabetes.

SD A1cCare has successfully completed the NGSP (National Glycohemoglobin Standardization Program, USA) manufacturer certification.

SD A1cCare has been certified every year since it launched. SD A1cCare is considered to be traceable to the DCCT (Diabetes Control and Complications Trial) reference method.



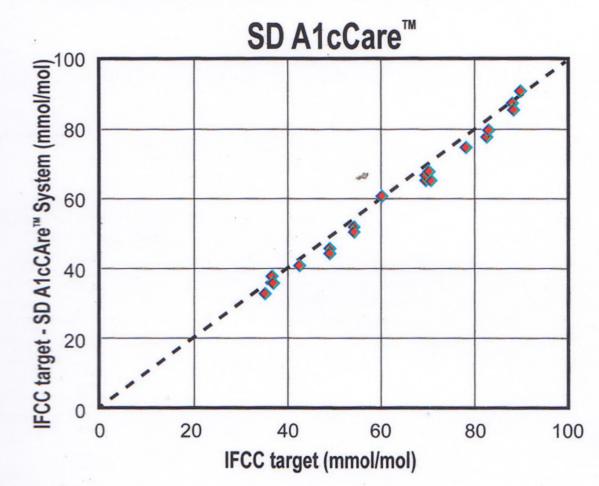
<sup>\*</sup> Criteria for NGSP manufacturer certification: 37/40 HbA1c result (single results) must be within +6% of the NGSP SRL mean

### Evaluation Report (IFCC)

Test Method(Y): SD A1cCare System

Comparative Method(X): HPLC, Mass spectrometry or capillary electrophoresis

Unit of Measurement: mmol/mol (IFCC)

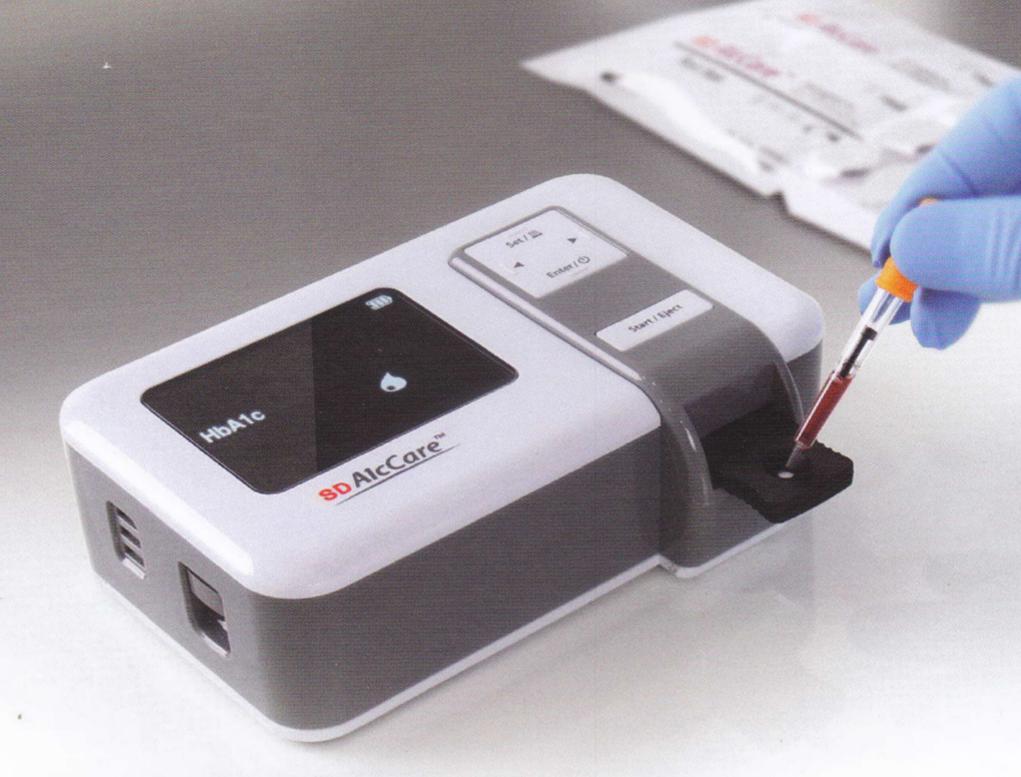


Issue	SD A1cCare™ System	
Interpretation deviation from IFCC reproducibility linearity	Excellent Excellent Excellent	
Accuracy deviation from IFCC at 30 mmol/mol IFCC level at 60 mmol/mol IFCC level at 90 mmol/mol IFCC level	-2.0 mmol/mol -1.8 mmol/mol -1.7 mmol/mol	
Reproducibility coefficient of variation	1.45%	
Linearity correlation coefficient	0.9954	

### The Brilliant HbA1c System

## SD A1cCare<sup>TM</sup>

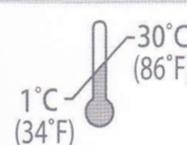
A1cCare is an optimized system applicable at the point-of-care testing field.



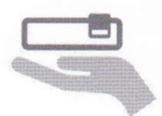
#### Advantages of SD A1cCare



- Performance
- Accuracy: R<sup>2</sup> ≥ 0.98
- Precision: CV < 3%



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



- Convenience
- Small size
- Batteries usable



- A1c Control material
- For single use
- Storage at RT for 18 months

### Specifications

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

#### **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 \*\* Search "A1cCare" on Youtube.

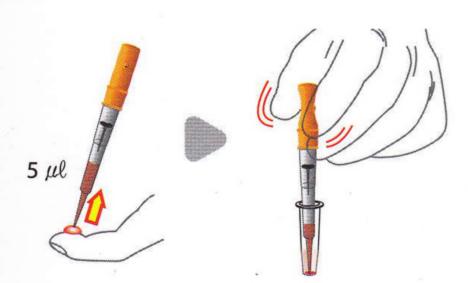
Insert a test panel.



Apply mixed sample to the test panel.



**2** Take 5  $\mu\ell$  of blood sample and mix it with buffer solution.



Check the result after 3 minutes.



You Tube \*\* Search "A1cCare" on Youtube.

For more information on

SD A1cCare™

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