



SEKURE<sup>®</sup>  
HbA1c  
Enzymatic Assay

Gold Standard HbA1c Performance  
for Clinical Chemistry Systems

SEKURE<sup>®</sup>

# SEKURE<sup>®</sup> HbA1c Enzymatic Assay

“The A1C assay is the test of choice for the chronic management of diabetes and is now being recommended for its diagnosis.”

International Expert Committee with members appointed by the American Diabetes Association, the European Association for the Study of Diabetes, and the International Diabetes Federation

## Diabetes is a Global Disease

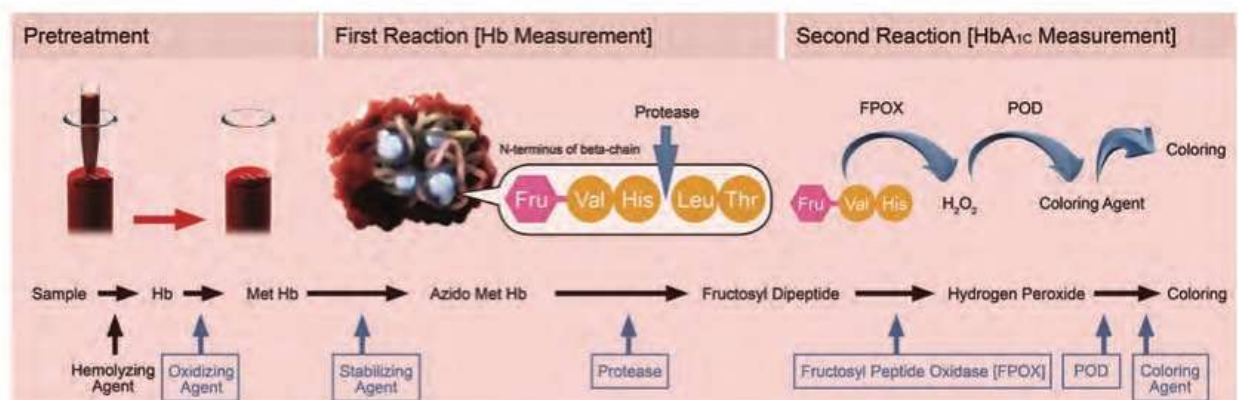
- Diabetes is a global epidemic that continues to grow in both its human impact and the financial burden it places on healthcare systems around the world
- HbA1c plays a prominent role as an aid to diagnosis and in the management of diabetes, without the variability often found in glucose testing
- It is critical to have a method that provides superior performance that can be accessed without the need for specialized instruments or procedures

## The Benefits of an Enzymatic Method

- SEKURE<sup>®</sup> enzymatic method targets the HbA1c molecule exceptionally well, providing performance comparable to gold-standard methods, like HPLC
- The enzymatic method is latex-free and does not require special cleaning or frequent cuvette replacement, like some latex-based methods can
- HbA1c can be run as a single-channel assay, where total hemoglobin and A1c are both measured in the same cuvette, minimizing reagent usage and maximizing instrument throughput

## Improved Workflow

- Online pretreatment simplifies laboratory workflow by sampling directly from the blood collection tube on the analyzer—no offline handling needed
- Reagents are liquid, ready-to-use and can be placed directly on the SK<sup>™</sup>500



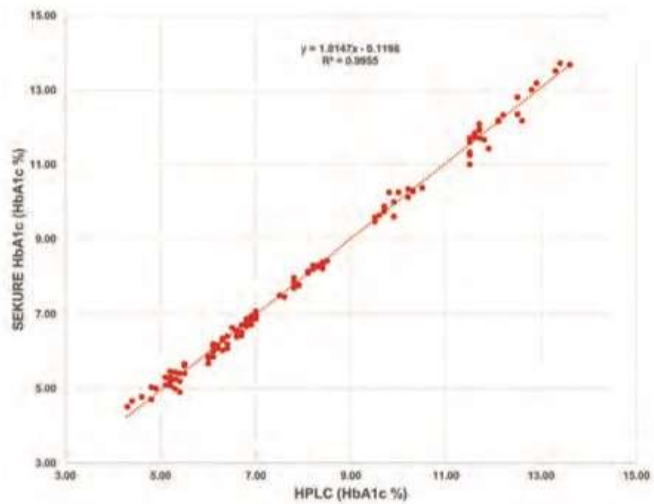
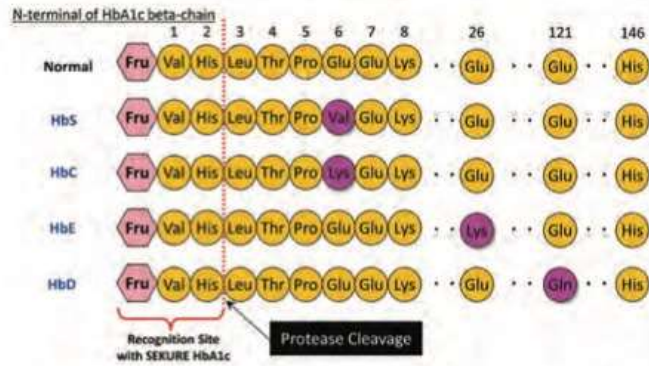


### Minimize Interference from Hemoglobin Variants

Heterozygous hemoglobin variants do not interfere with the SEKURE® HbA1c assay because the enzymatic protease cleavage occurs before the location of the amino acid substitutions for these variants. HbA1c concentration is measured using the "Fru-Val-His" amino acid combination.

### Analytical Performance: SK™500 Correlation vs. HPLC

Method Comparison studies with the SK™500 show excellent correlation to HPLC, which is considered by many to be the gold standard for HbA1c testing.



### Maintain Performance in the Presence of Interferents

#### ENDOGENOUS SUBSTANCES

POTENTIAL INTERFERENT	TESTED CONCENTRATION
Acetylated Hemoglobin	50.8 mg/dL
Ascorbic Acid	3.0 mg/dL
Bilirubin, Conjugated	18 mg/dL
Bilirubin, Unconjugated	18 mg/dL
Carbamylated Hemoglobin	65 mg/dL
Glucose	1000 mg/dL
Rheumatoid Factor	200 IU/mL
Total Protein	22 g/dL
Triglycerides	3000 mg/dL
Urea	667 mg/dL
Vitamin E	8.6 mg/dL

#### MEDICATIONS

POTENTIAL INTERFERENT	TESTED CONCENTRATION
Acarbose	50 mg/dL
Acetaminophen	20 mg/dL
Acetylsalicylate	50.8 mg/dL
Atorvastatin	600 µg Eq/L
Captopril	0.5 mg/dL
Chlorpropamide	74.7 mg/dL
Cyanate	65 mg/dL
Furosemide	6.0 mg/dL
Gemfibrozil	7.5 mg/dL
Ibuprofen	50 mg/dL
Insulin	450 µU/mL
Losartan	5.0 mg/dL
Metformin	5.1 mg/dL
Nicotinic Acid	61 mg/dL
Propranolol	0.2 mg/dL

Data collected on SK™500 Clinical Chemistry System

SEKURE® HbA1c maintains its performance in the presence of many common endogenous substances and medications

# SEKURE® HbA1c Enzymatic Assay

## Available on the SK™500 Clinical Chemistry System

- SEKURE® HbA1c is optimized for the SK500 Clinical Chemistry System as a single channel assay with online pretreatment
- Also configurable on many other systems



## Benefits of SEKURE® HbA1c Enzymatic Assay

- Exceptional performance eliminates the need for a dedicated analyzer
- Online pretreatment maximizes workflow and productivity
- Consistent performance without the need to replace cuvettes
- Configurable to many clinical chemistry systems
- Long onboard bottle stability eliminates reagent waste

## SPECIFICATIONS

<b>Precision</b>	1.4% @ 5.01% HbA1c (NGSP) 0.8% @ 12.07% HbA1c (NGSP)	<b>Onboard Stability</b>	28 days (SK™500) 50 days (OEM)
<b>Linearity</b>	4.0 to 14.0% NGSP 20.02 to 129.43 IFCC	<b>Calibration Stability</b>	28 days (SK™500) 50 days (OEM)

PART NO.	ITEM	CONFIGURATION
SK350-60	SEKURE® HbA1c REAGENT KIT	R1 1 x 55mL; R2 1 x 18 mL; PreT 1 x 68mL
SK350-CAL	SEKURE® HbA1c CALIBRATOR SET	Low: 1 x 2mL; High: 1 x 2mL
SK350-QC	SEKURE® HbA1c CONTROL SET	Low: 1 x 2mL; High: 1 x 2mL
SK350-BLK	SEKURE® HbA1c BLANK SOLUTION	2 x 5mL

Currently not available for sale in all countries.

**SEKISUI**  
DIAGNOSTICS

Because every result matters™

### THE AMERICAS

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