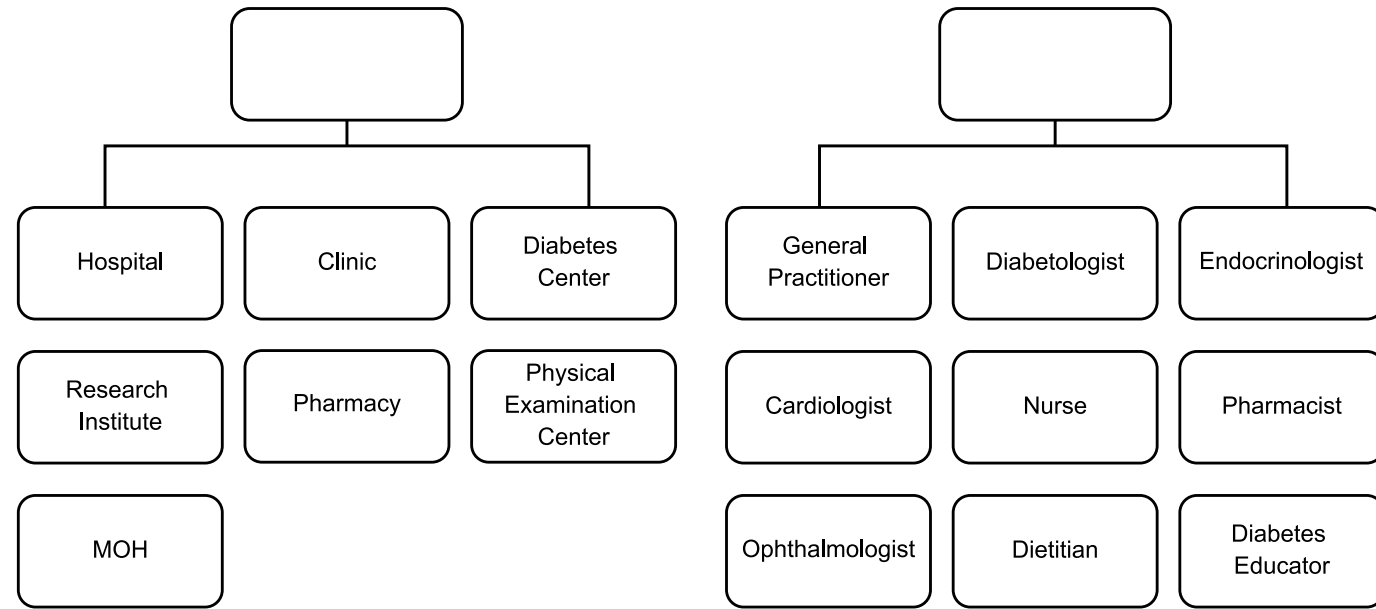
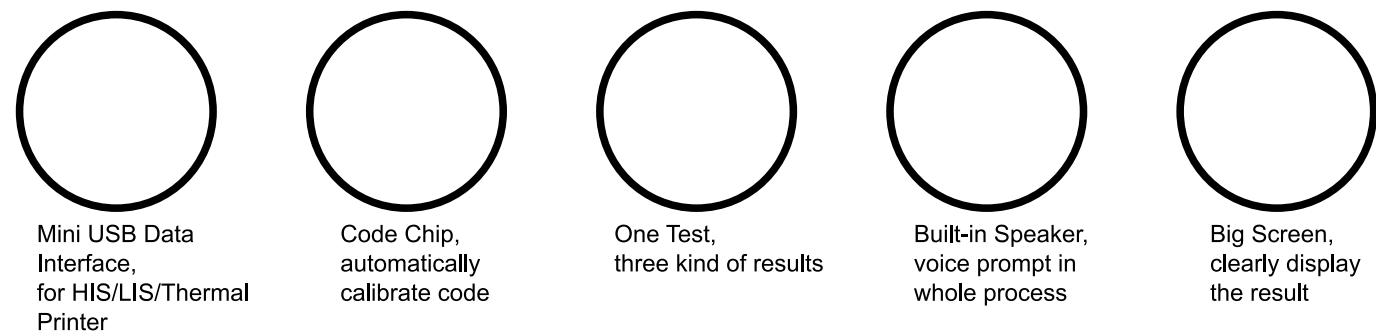
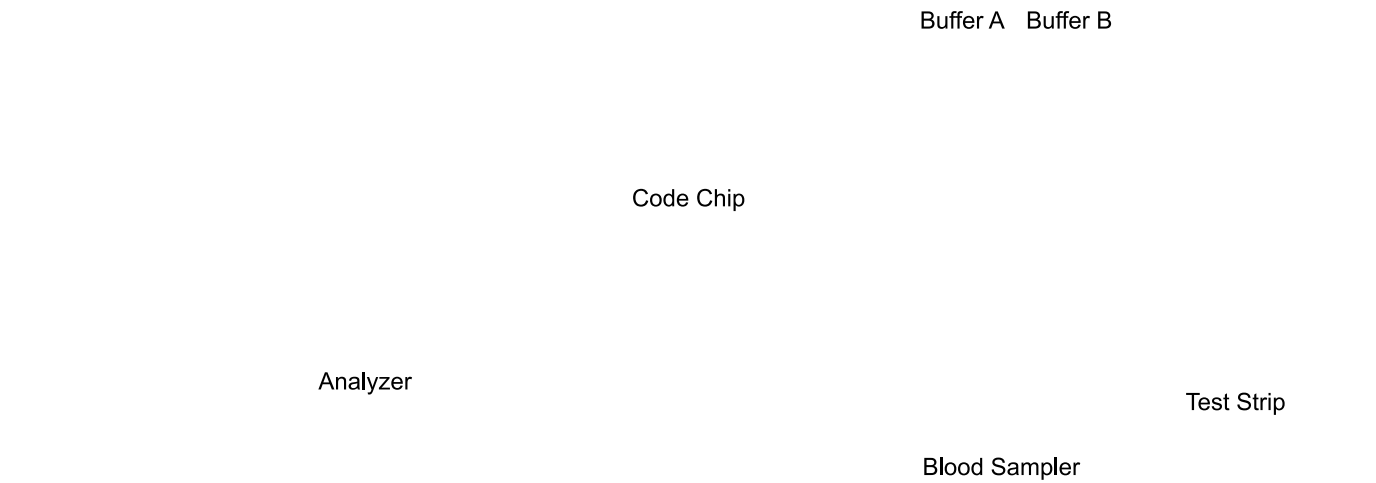


# Application Scope



**Note:**  
The Application Scope listed above is for reference only, the detailed Application Scope should depend on the market situations.

## Components



## Specifications

Specifications	Technical Parameters
Testing Principle	Boronate Affinity Chromatography
Testing Item	Glycohemoglobin (HbA1c)
Testing Range	4% -14%
Precision	CV<3% (HbA1c: 4.0%-6.5%)
Blood Sample	Fingertip blood or venous blood (EDTA Anticoagulation)
Blood Volume	About 3µL
Testing Time	About 5 minutes
Data Unit	Set in advance the data unit: NGSP%; IFCC mmol/mol
Voice Prompt	Voice prompt in whole process
Data Storage	1000 test results
Data Port	Mini USB data interface, can be connected with HIS/LIS system/thermal printer
Bluetooth Function	Optional
Power Required	AAA battery x4
Analyzer Dimension	61.5mm x 122.9mm x 24.5mm
Screen Size	47mm x 32mm
Weight	112g (Does not include battery)
Operating Condition	Temperature: 10°C~40°C; Humidity: 30%~70%
Storage Condition	Temperature: -10°C~50°C; Humidity: <80%

## Catalog

Product	Catalog No.	Contents
A1C EZ 2.0 Glycohemoglobin Analyzer	A1C-M21	1 Meter 1 User's Manual 1 Operation Guide 1 Cleaning and Maintenance Guide 1 Warranty Card
A1C EZ 2.0 Glycohemoglobin Test Kit	A1C-S22	25 Test Strips 1 Buffer A 1 Buffer B 25 Blood Sampler 1 Code Chip 1 Package Insert

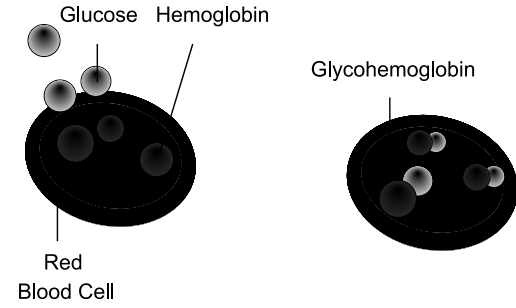
**Portable Testing of HbA1c**  
**Accurate Result with CV<3%**  
**Easy and Fast Operation**  
**Room Temperature Storage**

Joseph E. Ruggiero  
The CEO of BioHermes  
(Former Global Senior Director of Bayer Diabetes Care)

*It can speak!*

# Clinical Application

- HbA1c, formed in a non-enzymatic glycation pathway by hemoglobin's exposure to plasma glucose, reflects average glycemia over several months.
- As a primary technique to assess the effectiveness of diabetes management, HbA1c has strong predictive value for diabetes complications. Lowering HbA1c has been shown to reduce complications.
- HbA1c  $\geq 6.5\%$  (48 mmol/mol) is one of the criteria for diabetes diagnosis. Normal HbA1c range is 4.0-5.7% (20-39 mmol/mol), while 5.7-6.4% (39-46 mmol/mol) is considered as prediabetes.
- Point-of-care testing for HbA1c provides the opportunity for more timely treatment changes.



- NGSP and IFCC double certificates
- Boronate Affinity Chromatography technology, no interference from HbF, HbE and other variable and unstable Hb
- Accurate results with CV<3%



- Room temperature storage for all components
- 3 steps easy operation
- Only about 3 $\mu$ L of capillary or venous blood sample




- No preheat needed before testing
- No manual calibration needed
- Get the result within 5 minutes



**International Patents**

# Advantages

**IFCC Certificate**  
(International Federation of Clinical Chemistry)



**NGSP Certificate**  
(National Glycohemoglobin Standardization Program)



# Accurate Results

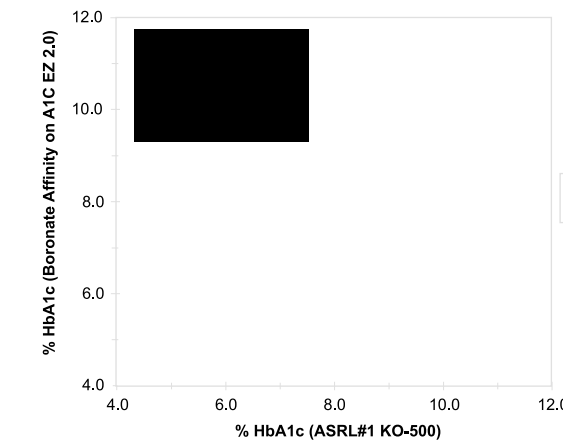
## Method Comparison Evaluation Report

Criteria for NGSP Manufacturer certification: 37/40 HbA1c results (single results) must be within  $\pm 6\%$  of the NGSP SRL mean (mean of duplicate results): Your method's results were within the NGSP criteria for Manufacturer Certification.

Method	#within 6%	Pass 37/40 Y/N
Boronate Affinity on A1C EZ 2.0	40	Y

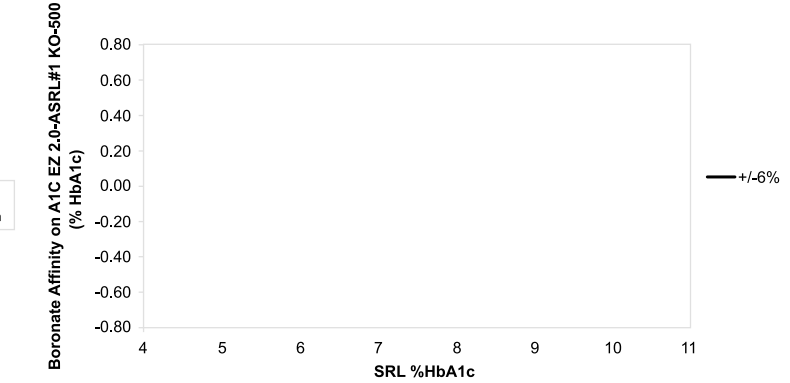
## Scatter Plot

Biohermes Bio & Medical Technology Co., Ltd.  
Boronate Affinity



## Bias Plot

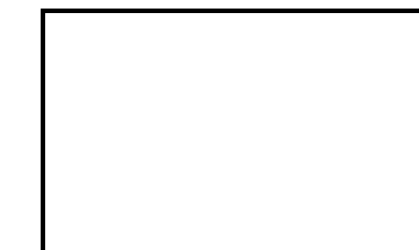
Boronate Affinity on A1C EZ 2.0 ASRL#1  
KO-500



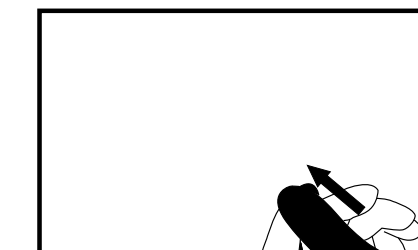
Reference: NGSP Method Comparison Evaluation Report 2016

## Operation Guide

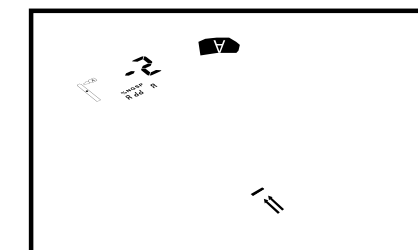
### Operation Guide



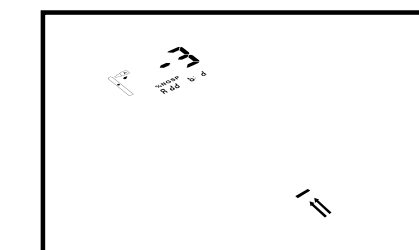
- Disinfect the fingertip
- Insert the code chip
- Turn on the analyzer



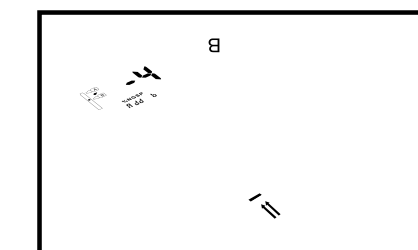
- Carefully insert the test strip
- Prick the fingertip
- Absorb the blood with sampler



- Vertically add 3 continuous drops of buffer A



- Press the sampler thread onto the strip



- Vertically add 2 continuous drops of buffer B



- Read the test result

### PATIENT/DISEASE FEATURE

More Stringent (e.g., 6.5%)  $\leftarrow$  **HbA1c 7%**  $\rightarrow$  Less Stringent (e.g., 8.0%)

Risks potentially associated with hypoglycemia and other adverse effects

Low  High

Disease duration

Newly diagnosed  Long-standing

Life expectancy

Long  Short

Important comorbidities /Established vascular complications

Absent  Few/mild  Severe

Patient attitude and expected treatment efforts

Highly motivated, adherent, excellent self-care capacities  Less motivated, nonadherent, poor self-care capacities

Resources and support system

Readily available  Limited

Usually not modifiable

Potentially modifiable

### Note:

- The HbA1c goal for pregnancy is 6-6.5% (42-48 mmol/mol); 6% (42 mmol/mol) may be optimal if no significant hypoglycemia, while the goal may be relaxed to 7% (53 mmol/mol) if necessary to prevent hypoglycemia.
- A target of 7.5% (58 mmol/mol) is recommended across all pediatric age-groups; a lower goal (7.0% [53 mmol/mol]) is reasonable if no excessive hypoglycemia.

Group	Test Frequency
Meet the treatment goals and have stable glycemic control	At least twice a year
Not meet glycemic goals or therapy changed	Every 3 months
Unstable or highly intensively managed patients (e.g., pregnant women with type 1 diabetes)	More frequently than every 3 months
High diabetes risk groups (e.g., obesity, first-degree relative with diabetes, etc.)	Test routinely, like once every 3 years

### Note:

- HbA1c testing should be performed routinely in all patients with diabetes---at initial assessment and as part of continuing care.
- The frequency of HbA1c testing should depend on the clinical situation, the treatment regimen, and the clinician's judgment.