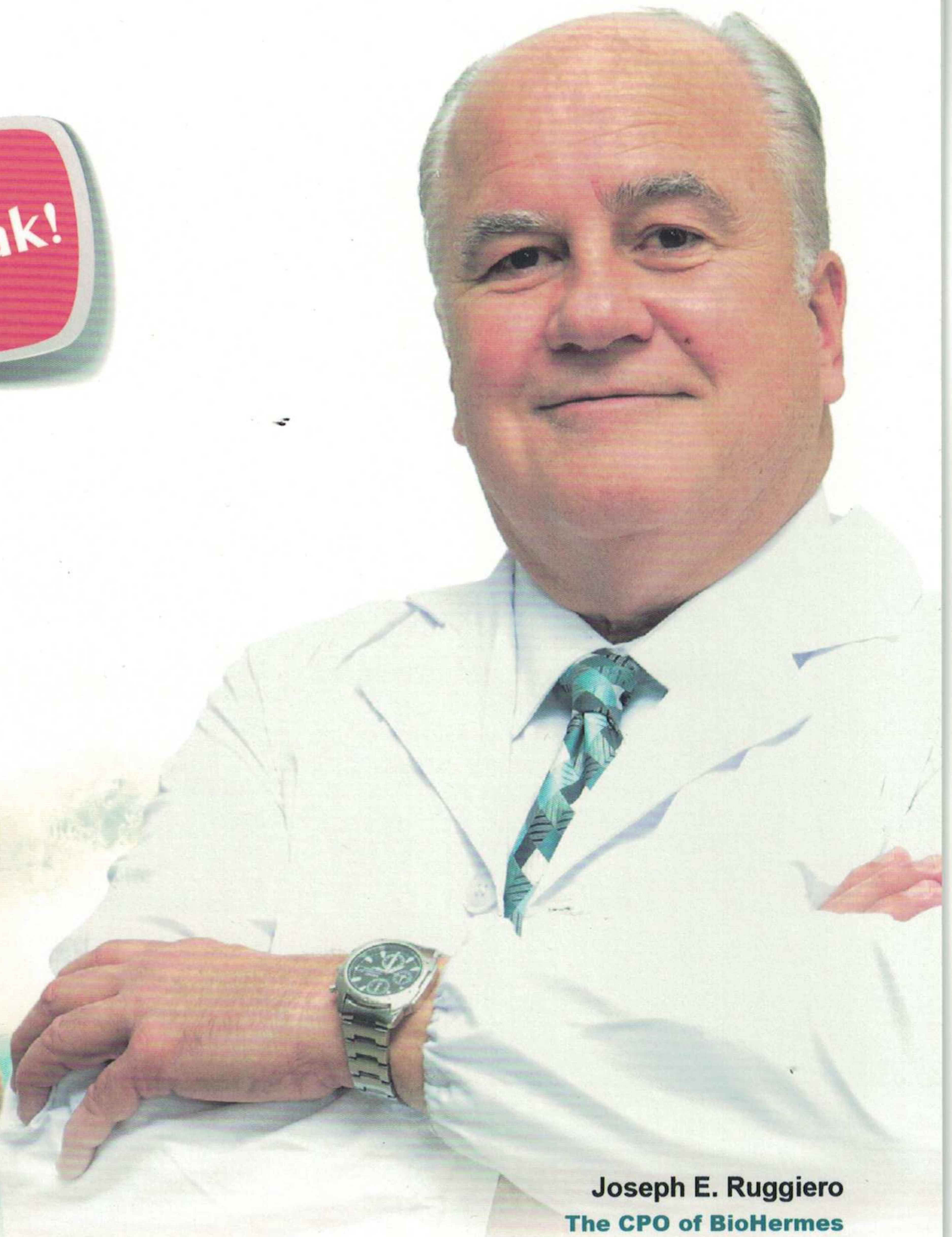


A1C EZ 2.0

Glycohemoglobin Analysis System
(Boronate Affinity Chromatography)



It can speak!



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

Unique Handheld HbA1c Analyzer for Better Diabetes Care

Portable Testing of HbA1c

Accurate Result with CV<3%

Easy and Fast Operation

Room Temperature Storage



Management System
EN ISO
13485:2012

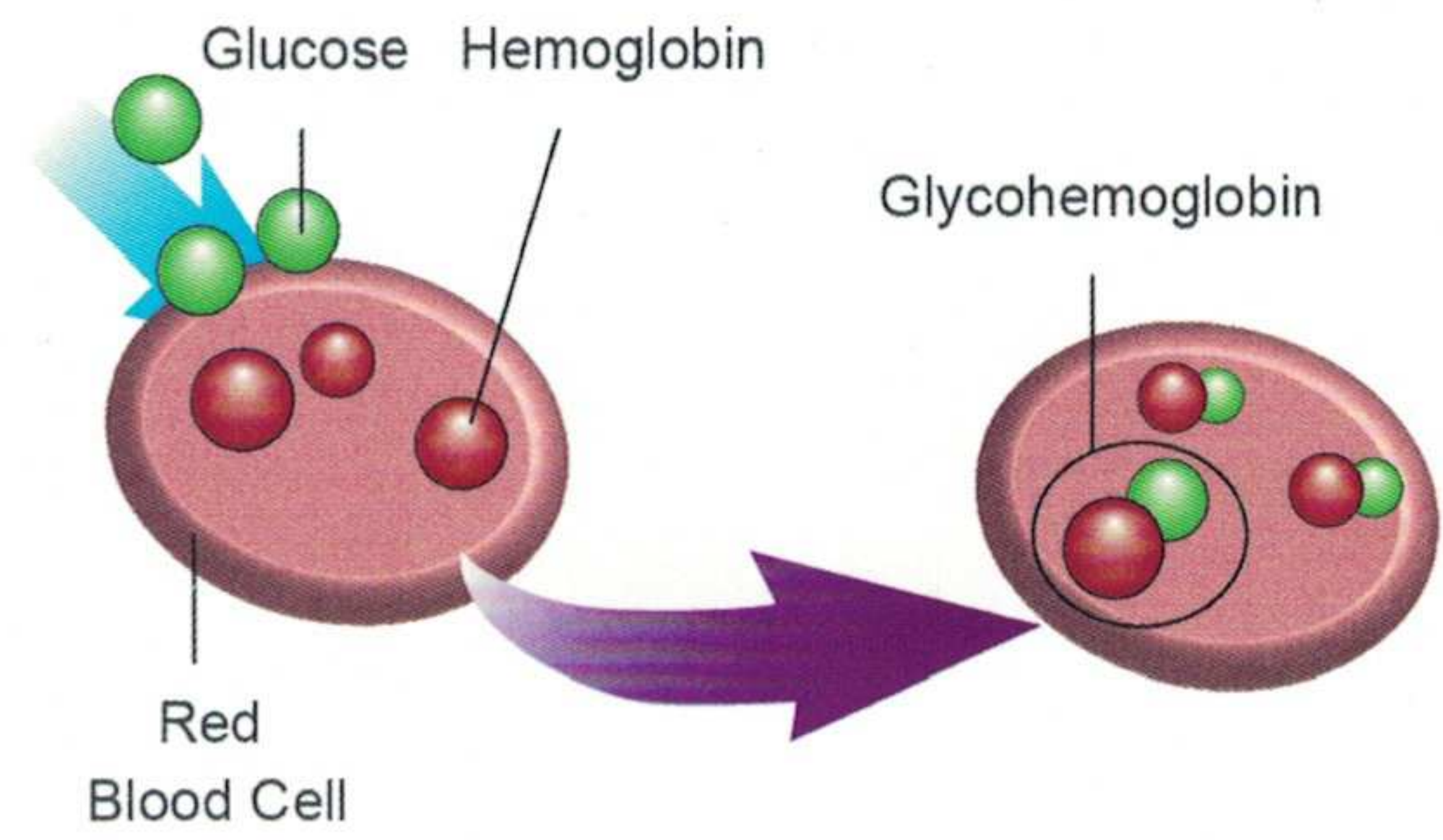


www.tuv.com
ID 000042900

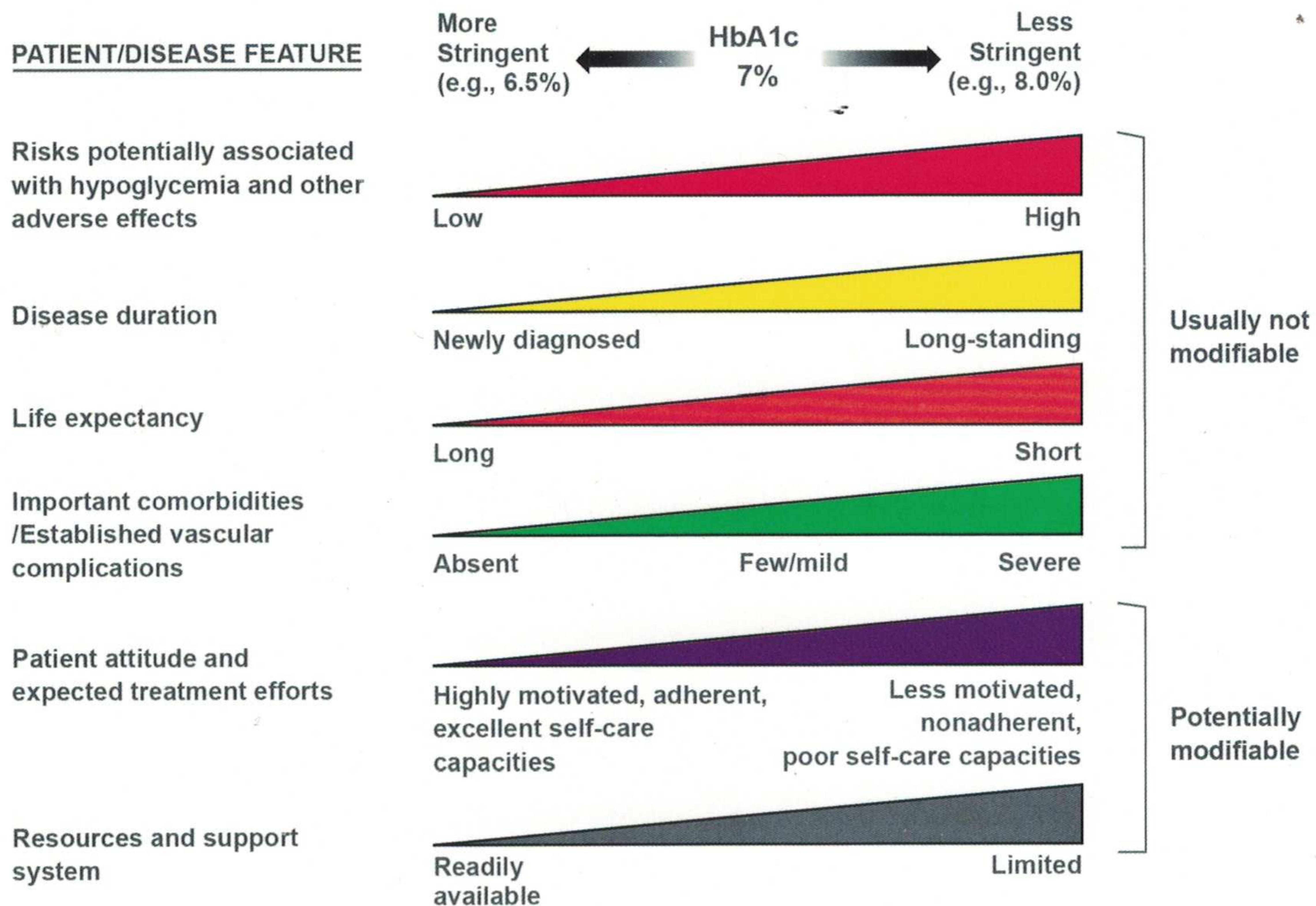
Clinical Application

What is HbA1c

1. HbA1c, formed in a non-enzymatic glycation pathway by hemoglobin's exposure to plasma glucose, reflects average glycemia over several months.
2. 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.
3. 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.
4. Point-of-care testing for HbA1c provides the opportunity for more timely treatment changes.



HbA1c Goals



Note:

1. 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.
2. 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.

HbA1c Test Frequency

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:

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

Advantages



Accurate

- 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%



Convenient

- Room temperature storage for all components
- 3 steps easy operation
- Only about 3µL of capillary or venous blood sample



Fast

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

IFCC Certificate (International Federation of Clinical Chemistry)



NGSP Certificate (National Glycohemoglobin Standardization Program)



International Patents



The technology is patented in USA, Canada, France, Germany, Great Britain, Italy, Japan, China, South Africa, Mexico, Brazil, Israel, India, etc.

Accurate Results



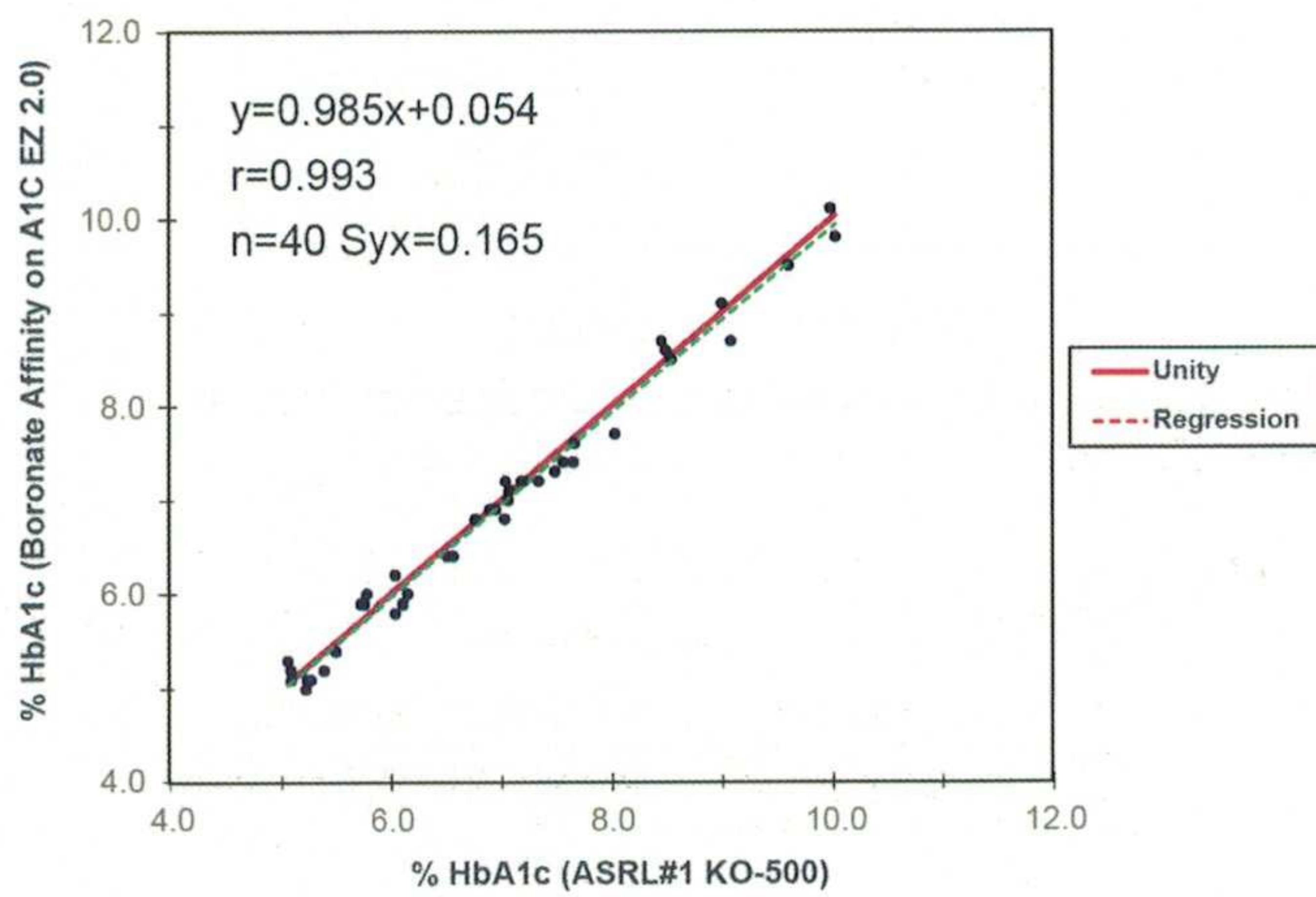
Method Comparison Evaluation Report

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

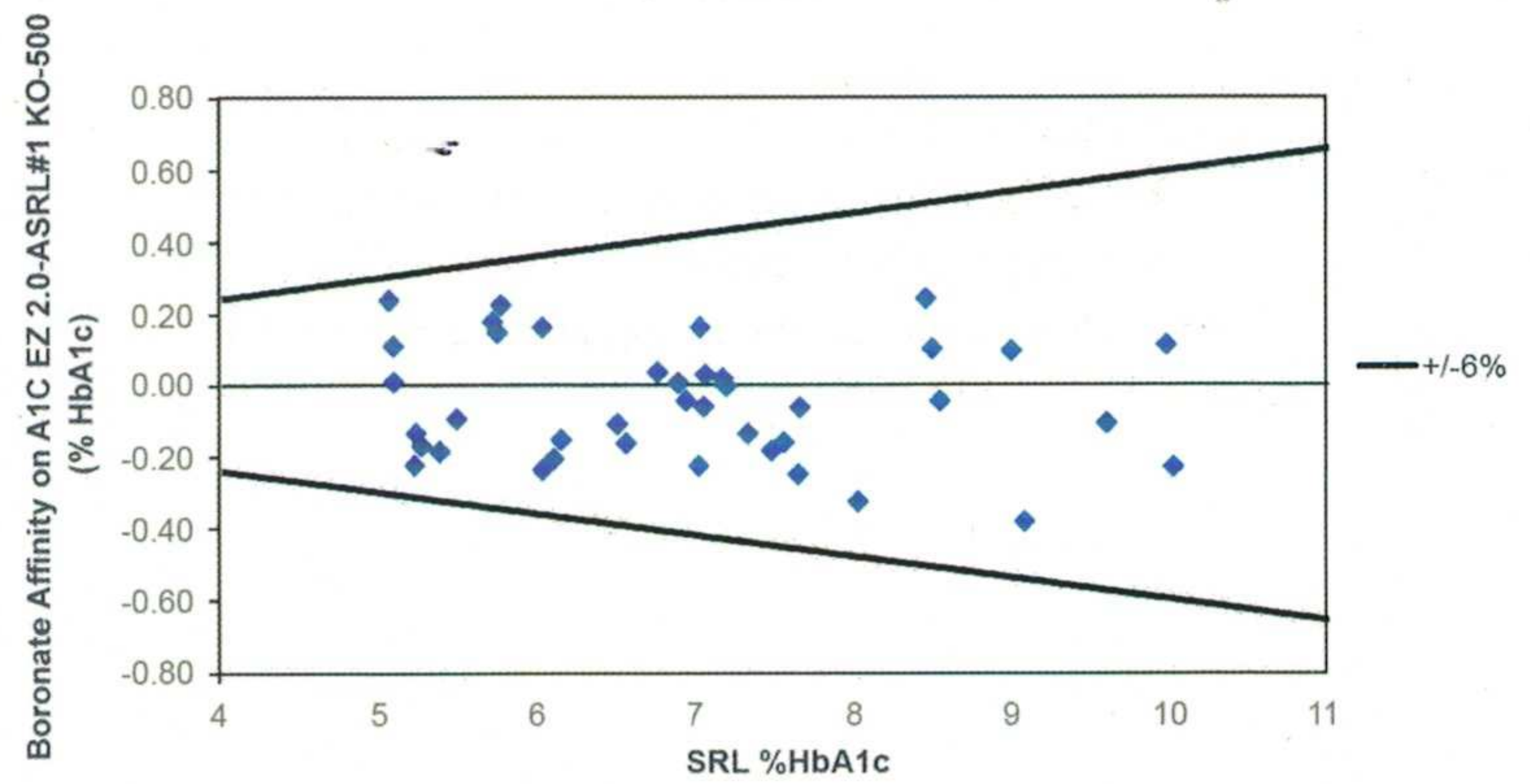
Scatter Plot

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



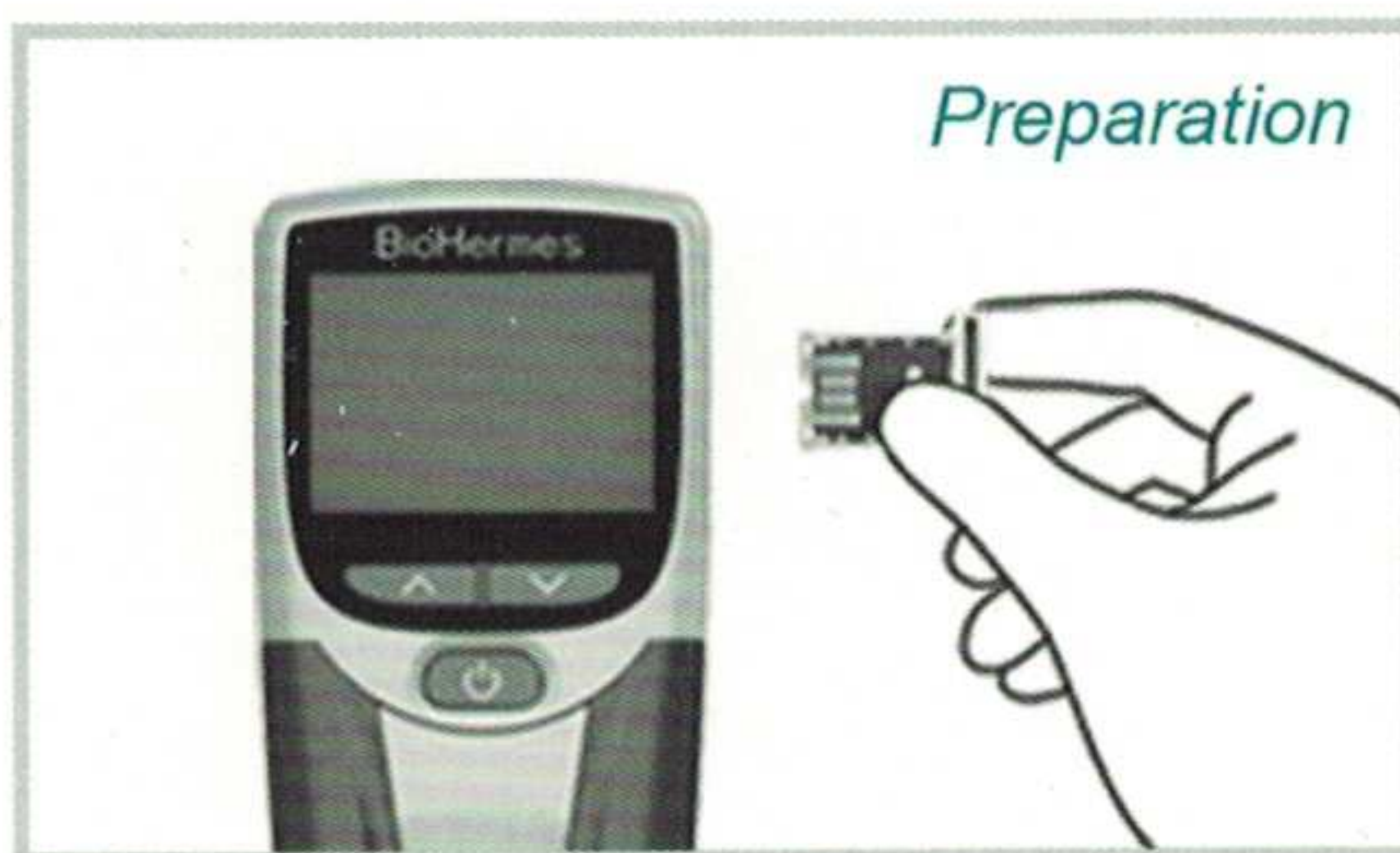
Bias Plot

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



Reference: NGSP Method Comparison Evaluation Report 2016

Operation Guide



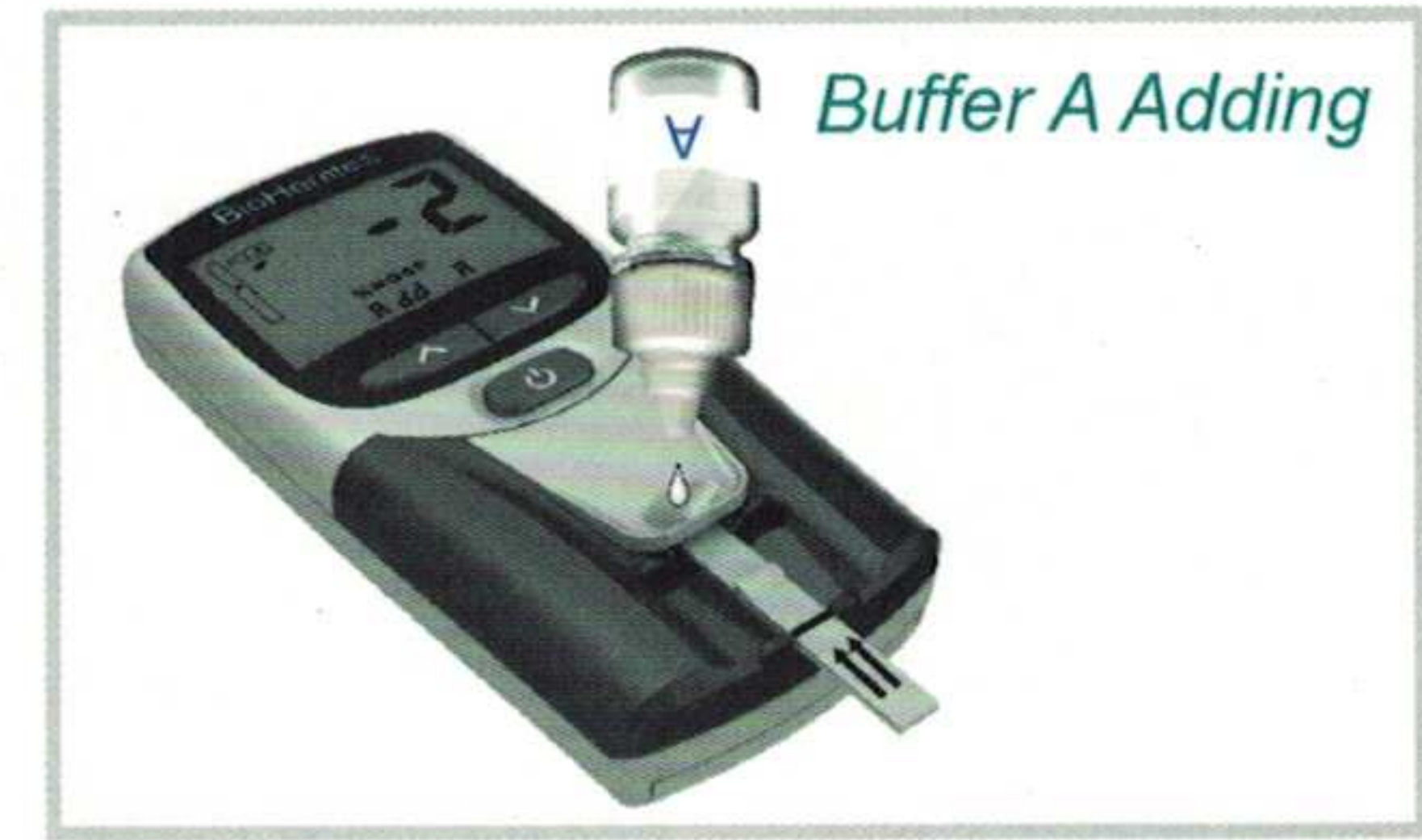
Preparation

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



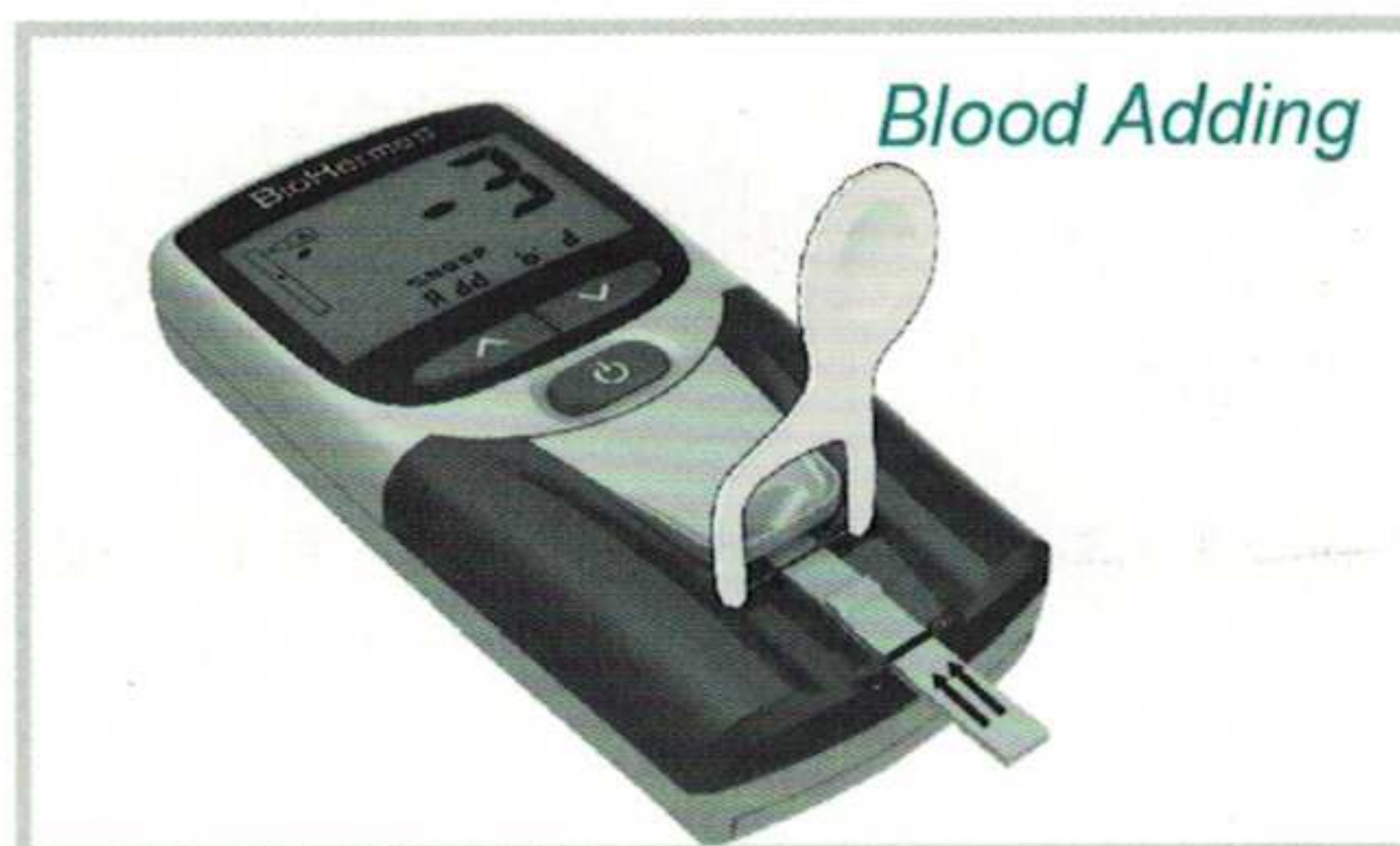
Strip Insertion

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



Buffer A Adding

- Vertically add 3 continuous drops of buffer A



Blood Adding

- Press the sampler thread onto the strip



Buffer B Adding

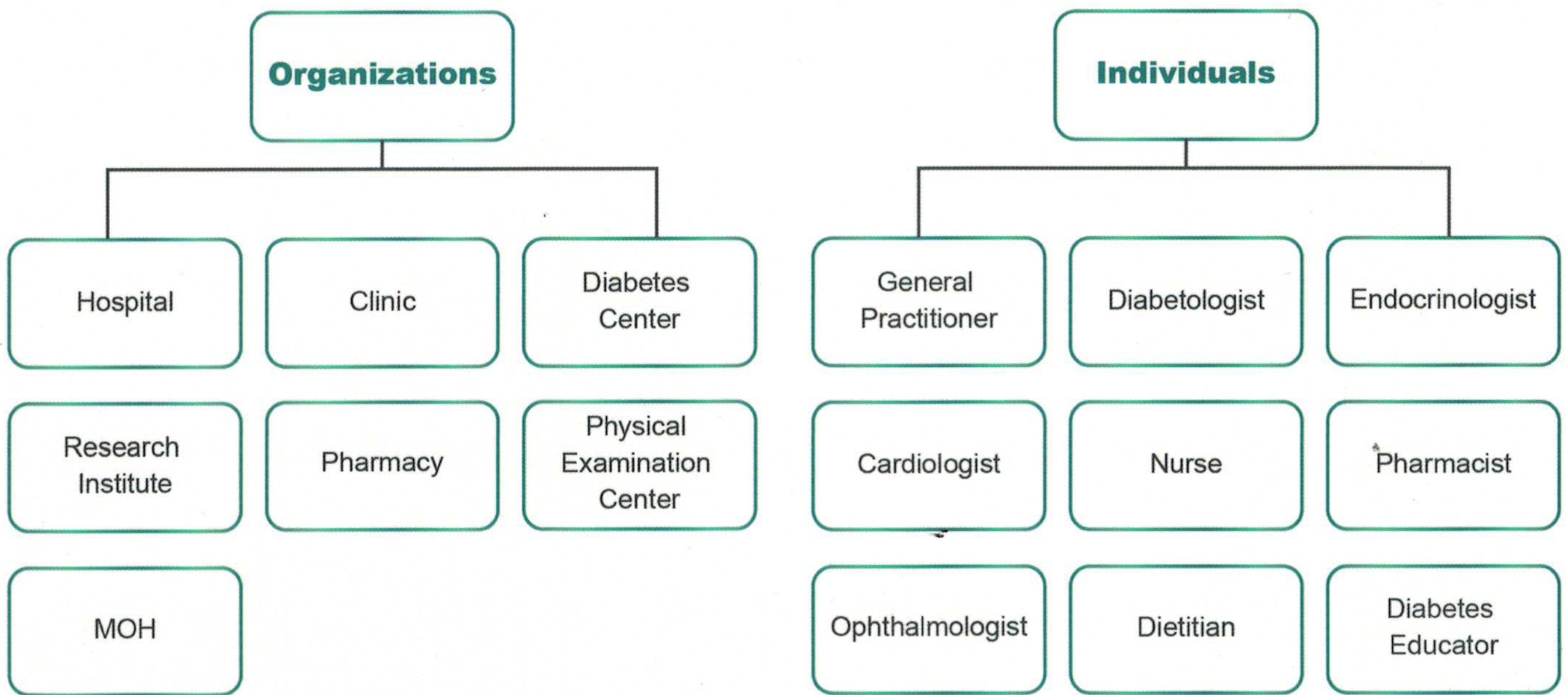
- Vertically add 2 continuous drops of buffer B



Result Reading

- Read the test result

Application Scope



Note:

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

Components

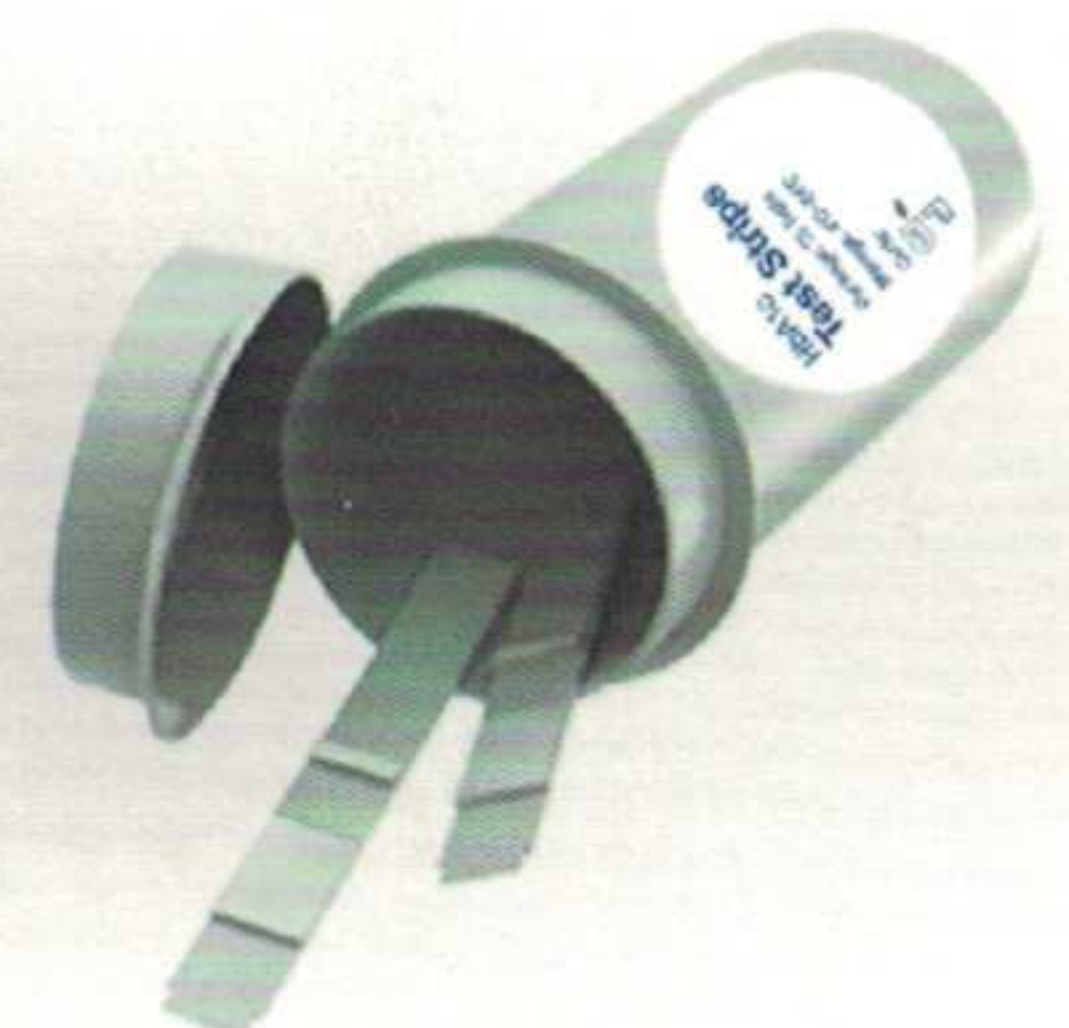


Analyzer



Code Chip

Buffer A Buffer B

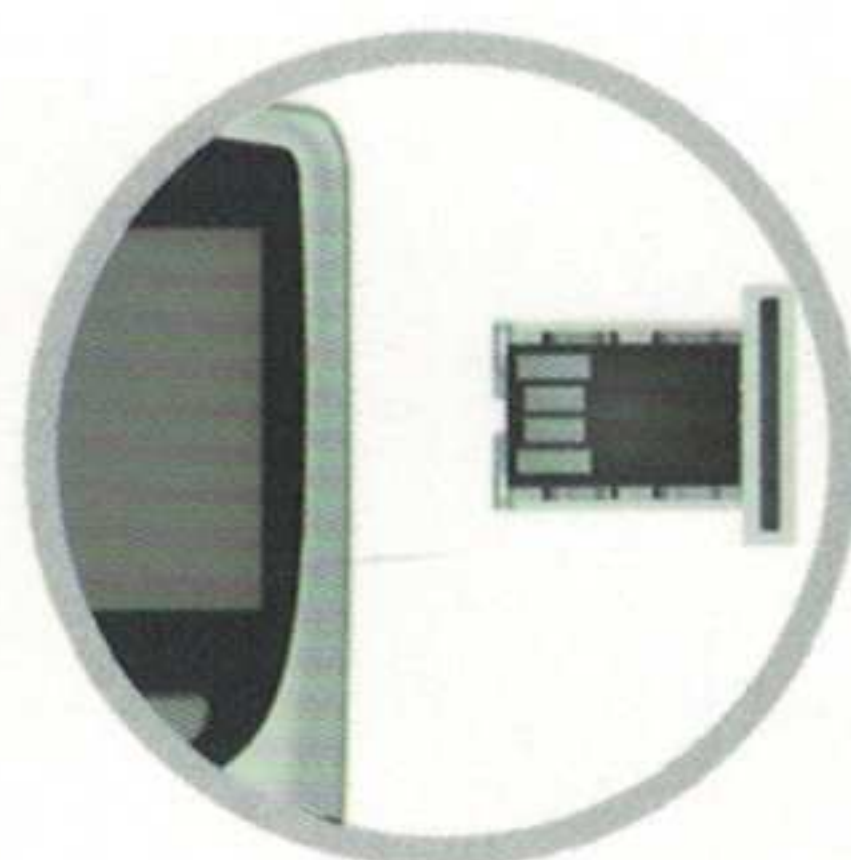


Blood Sampler

Test Strip



Mini USB Data Interface, for HIS/LIS/Thermal Printer



Code Chip, automatically calibrate code



One Test, three kind of results



Built-in Speaker, voice prompt in whole process



Big Screen, clearly display the result

A1C EZ 2.0

Unique Handheld POCT HbA1c Analyzer



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 3 μ L
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

Wuxi Biohermes Bio & Medical Technology Co., Ltd.

136 Meiliang Road, Mashan, Wuxi, Jiangsu, 214092, China

Tel: +86-510-8583-5879 Fax: +86-510-8583-7563 Email: info@biohermes.com.cn

www.biohermes.com