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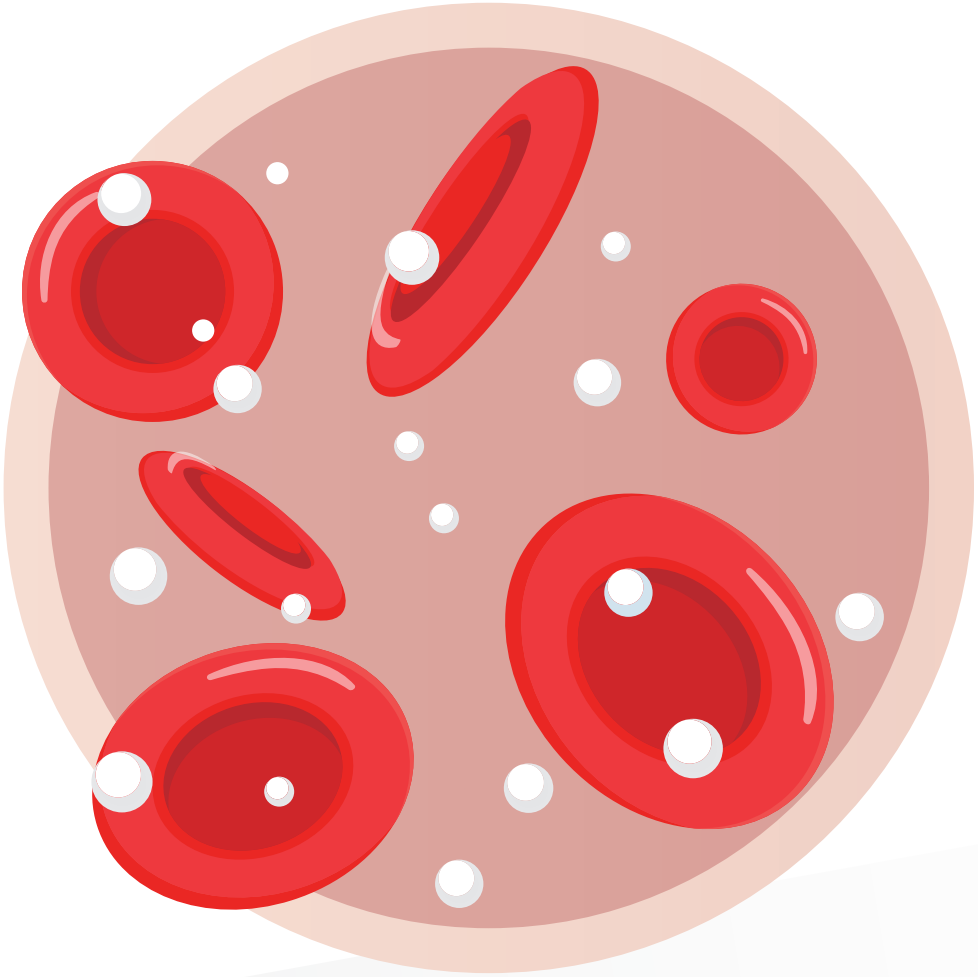
ChemBook

Discover how Mindray Chemistry System can give you a reliable HbA1c result



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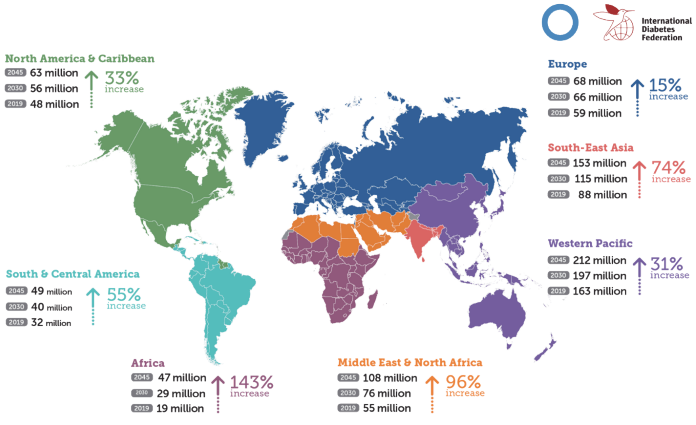
Content

HbA1c : The Core Marker of Diabetes Mellitus Management

Diabetes Mellitus (DM) is a global health challenge. One in 11 adults (20-79 years) were reported to have DM by the International Diabetes Federation (IDF) in 2019, and this proportion is on the rise as society changes and the population ages. [1] DM complications include a series of problems, such as nephropathy, retinopathy, and coronary artery disease.



IDF DIABETES ATLAS 2019

Predicted number of people (20-79 years) with diabetes globally [1]

Diagnosis, proper treatment, and glycemic control monitoring are essential to DM management. As a result, many laboratory tests have been introduced in practice, such as glycated hemoglobin (HbA1c), glycated protein (fructosamine, FUN), fasting plasma glucose, and 2-hour plasma glucose. Among them, HbA1c is widely recognized as a core test for DM management.

DM Diagnosis

According to the IDF, there are approximately 232 million people with undiagnosed DM worldwide. Many guidelines tend to suggest DM screening in the population with or without specific medical conditions, and HbA1c is a convenient test to meet this objective. [2] Unlike glucose tests, HbA1c is not affected by recent food intake, so patients do not have to fast or intake certain quantities of glucose before the test. Accompanied with medical history and some auxiliary evidence, doctors can make the DM diagnosis if the patient's HbA1c matches the criteria.

	HbA1c	Fasting Plasma Glucose	2-h Plasma Glucose
Diabetes	≥6.5% or ≥48 mmol/mol	≥ 126 mg/dL or ≥ 7.0 mmol/L	≥200 mg/dL or ≥ 11.1 mmol/L
Prediabetes	5.7-6.4% or 39-47 mmol/mol	100-125 mg/dL or 5.56-6.9 mmol/L	140-199 mg/dL or 7.8-11.0 mmol/L
Normal	<5.7% or < 39 mmol/mol	< 100 mg/dL or <5.56 mmol/L	< 140 mg/dL or <7.8 mmol/L

American Diabetes Association (ADA) criteria [3]

Therapeutic Monitoring

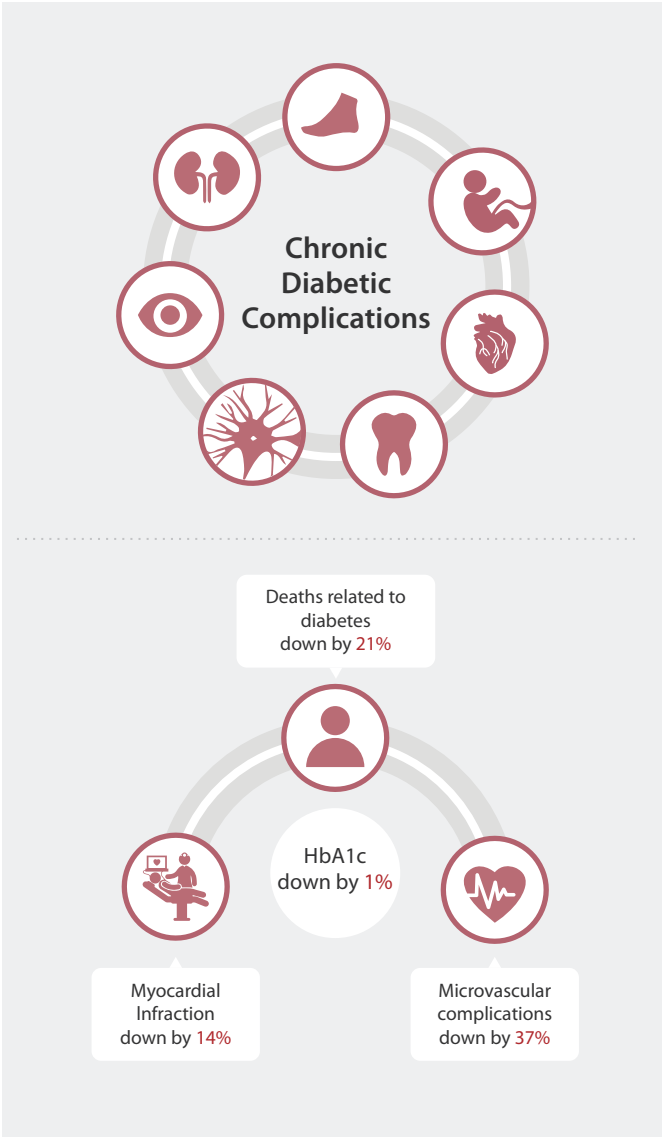
Once diagnosed, patients may receive treatment, such as lifestyle changes, medication, and/or insulin. Regardless of the treatment method, monitoring is crucial to holistically manage this disease. As HbA1c can reveal the average blood glucose over an approximate 3-month period, many guidelines have published HbA1c targets for glycemic control monitoring. These targets can be used to guide therapeutic improvements.

AACE-Recommended Glycemic Targets for Nonpregnant Adults [4]
Individualize on the basis of age, comorbidities, and duration of disease • ≤6.5% for most • Closer to normal for healthy adults • Less stringent for "less healthy" adults

AACE, American Association of Clinical Endocrinologists

ADA-Recommended Glycemic Targets for Nonpregnant Adults [5]
• <6.5% for patients who meet the following criteria: -Short duration of diabetes -Long life expectancy -No concurrent illness -Goal can be achieved without significant hypoglycemia or other adverse effects of treatment
• <7.0%, a reasonable goal for many patients
• <8.0% for patients who meet the following criteria: -History of severe hypoglycemia -Limited life expectancy -Advanced microvascular or macrovascular complications -Extensive comorbid conditions -Long-standing T2DM in which HbA1C goal has been difficult to achieve despite intensive efforts

HbA1c is an ideal marker for the assessment of glycemic control. Every small reduction in HbA1c can significantly reduce the risks of DM-related morbidity and mortality. The test frequencies are every 6 months for well-controlled patients, and every 3 months for poorly-controlled patients, or patients who are making changes to their therapeutic regimen. [6]



Common DM complications and the significance of HbA1c reductions [7, 8]

Summary

Since HbA1c was first separated in 1958, a series of studies have proved it to be highly valuable in the diagnosis and monitoring of DM. As a core marker recommended by multiple guidelines, HbA1c tests are much easier for patients to complete, much faster for laboratory technicians to analyze, and much more reliable for doctors to use to make clinical decisions.

References

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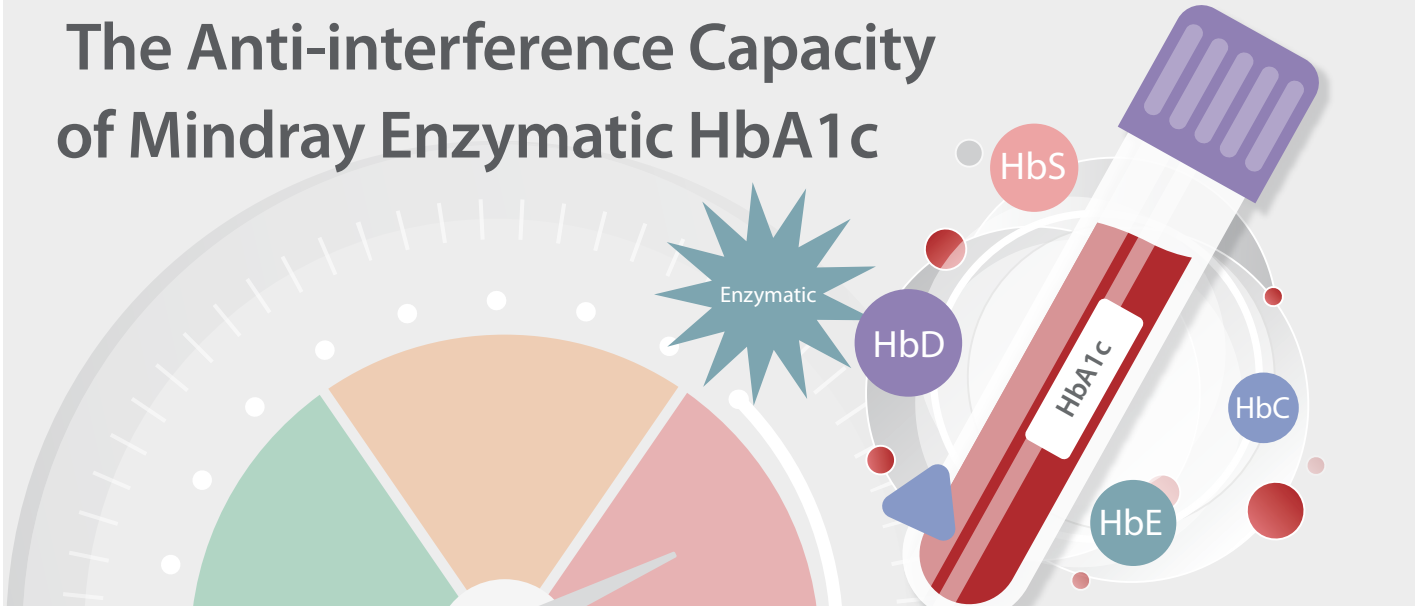
[8] Stratton IM, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. BMJ 321:405–412, 2000

The Anti-interference Capacity of Mindray Enzymatic HbA1c



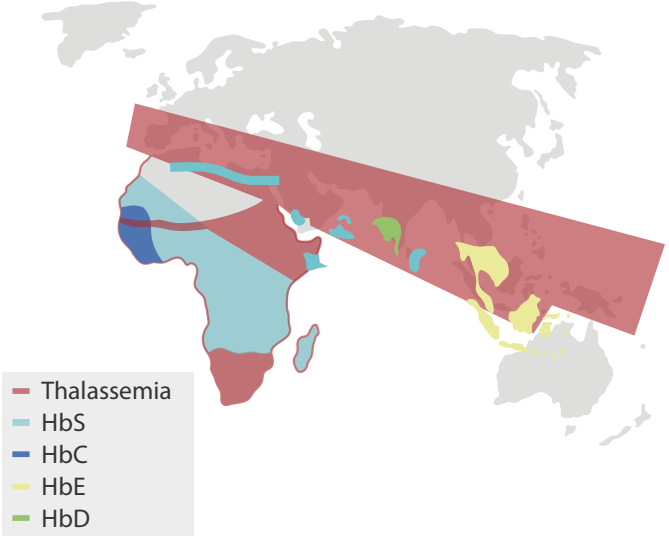
HbA1c, first separated in 1958, is fast becoming the core test for diabetes mellitus screening, diagnosis and therapeutic monitoring. Recognized as the standard tool for clinical practice, it has many advantages, such as being non-fasting, easy to use, and able to reflect the glycemic control over a period of 3-4 months.

Variants	Location	Substitution	Mass shift (Da)
HbS	β6	Glu → Val	-29.9745
HbC	β6	Glu → Lys	-0.9476
HbE	β26	Glu → Lys	-0.9476
HbD	β121	Glu → Gln	-0.9840

Structures of Common Hemoglobin Variants [2]

Interference Caused by Hemoglobin Variants

The IFCC working group has defined HbA1c as Hb which has been irreversibly glycated at one or both N-terminal valines of the beta-chains. [1] The commonly seen hemoglobin variants, such as HbS, HbC, HbE and HbD, have single amino acid substitutions in the beta-chains. Thereafter, each of these hemoglobin variants, depending on the method used, may cause an inaccurate HbA1c result because of analytic interference. Alternatively, an HbA1c value that is clinically misleading because of biologic variables affecting the interpretation of the result may be caused.

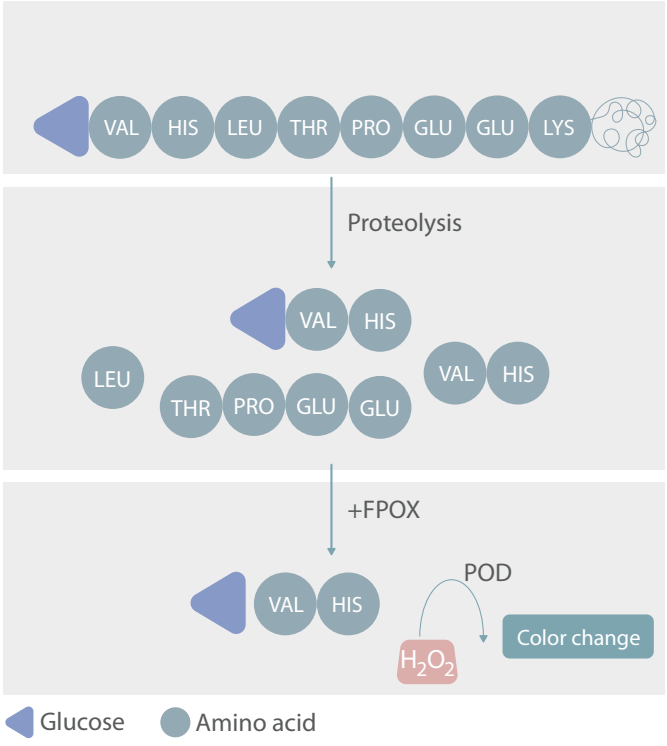


Distribution of Common Hemoglobin Variants [3]

Mindray Biochemistry HbA1c Testing

Amongst all testing methods for HbA1c, Mindray Biochemistry has chosen an enzymatic method because of certain methodological advantages. One such advantage is the anti-interference capacity against hemoglobin variants.

For the enzymatic method, whole blood samples are lysed and subjected to extensive proteolytic digestion. This process releases amino acids, specifically the glycated N-terminal amino acids from the hemoglobin beta-chains. The signal produced by the glycated N-terminal amino acids in a subsequent chromogenic reaction is used to calculate HbA1c. This method is unaffected analytically by the presence of Hb variants. [4]



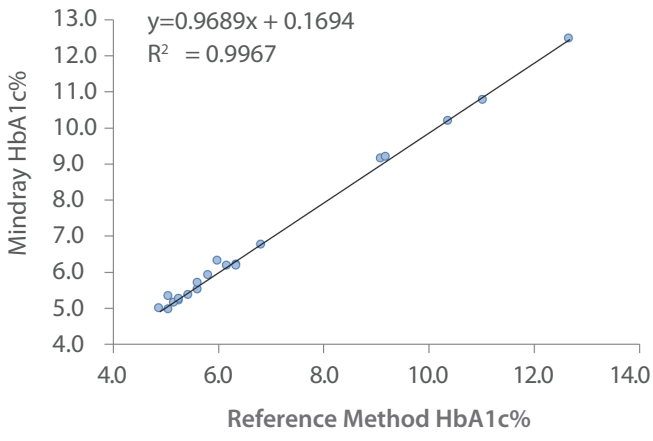
Enzymatic Assay for HbA1c Measurement

Mindray Enzymatic HbA1c Anti-interference Capacity

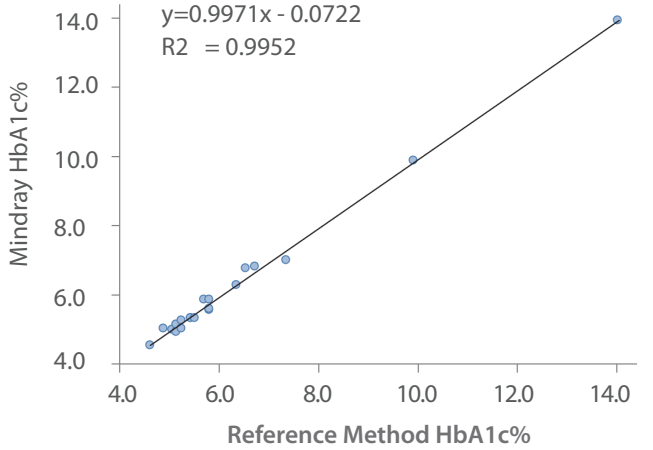
To reveal the anti-interference capacity, we have devised an internal study. Samples were collected from the Queen Beatrix Medical Center in The Netherlands, which houses the European Reference Laboratory for Glycohemoglobin, and the Primary Reference Laboratories for HbA1c standardization. The values of HbA1c were assigned by an IFCC calibrated affinity chromatography instrument. The percentage of HbS, HbC, HbE, and HbD were assigned by capillary electrophoresis and ion-exchanged HPLC. HbA1c (NGSP%) was measured on the BS-800M chemistry analyzer. No significant interference bias (i.e., greater than ± 5.0%) was observed for HbS, HbC, HbE and HbD. The data tested by Mindray and the target value assigned by European Primary Reference Laboratories were analyzed and listed in the following table and charts:

Variants	N	Range (%Variant)	Range (%HbA1c)	Relative Bias (Range Bias)	
				~6%HbA1c	~9%HbA1c
HbS	20	33~42%	4.9~12.7%	-0.2% (-3.2%~4.9%)	-0.1% (-0.2%~0.4%)
HbC	20	28~97%	4.6~14.0%	-1.8% (-4.3%~1.9%)	-2.8% (-5.0%~-0.6%)
HbE	25	19~94%	4.9~9.8%	-0.4% (-2.3%~3.4%)	-0.5% (-0.5%~-0.4%)
HbD	25	38~42%	5.2~9.7%	-1.2% (-3.3%~1.8%)	-0.3% (-3.8%~4.8%)

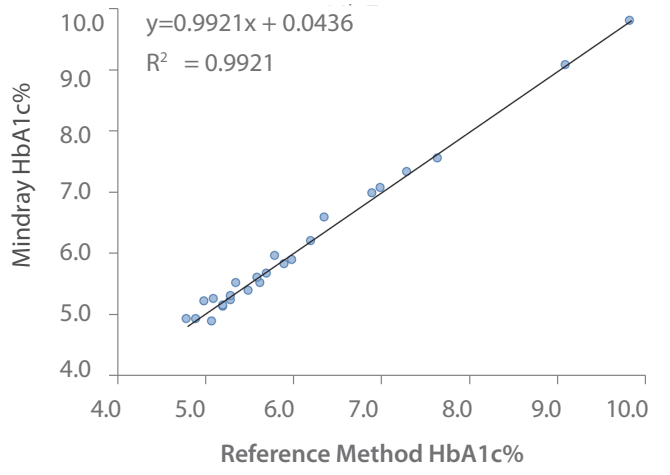
HbS



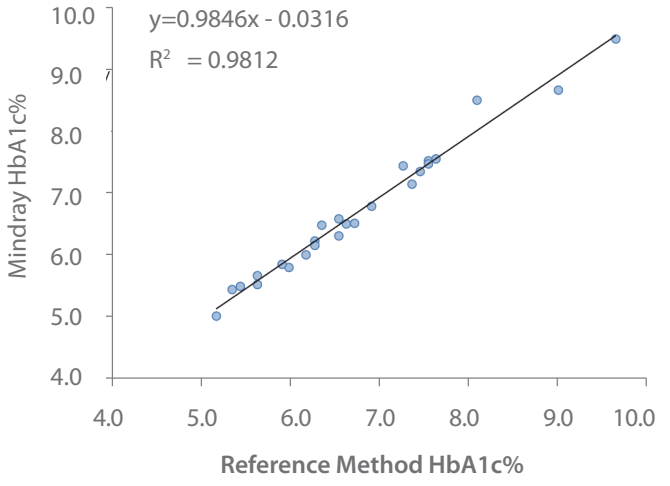
HbC



HbE



HbD



Summary

As a core marker recommended by multiple guidelines, HbA1c tests are highly significant in the screening, diagnosis, and monitoring of diabetes. Hb variants, especially the four most common variants worldwide (HbS, HbC, HbE, and HbD), can interfere the HbA1c testing result. The enzymatic method of the Mindray BS series chemistry system can effectively avoid interference from these variants.

References

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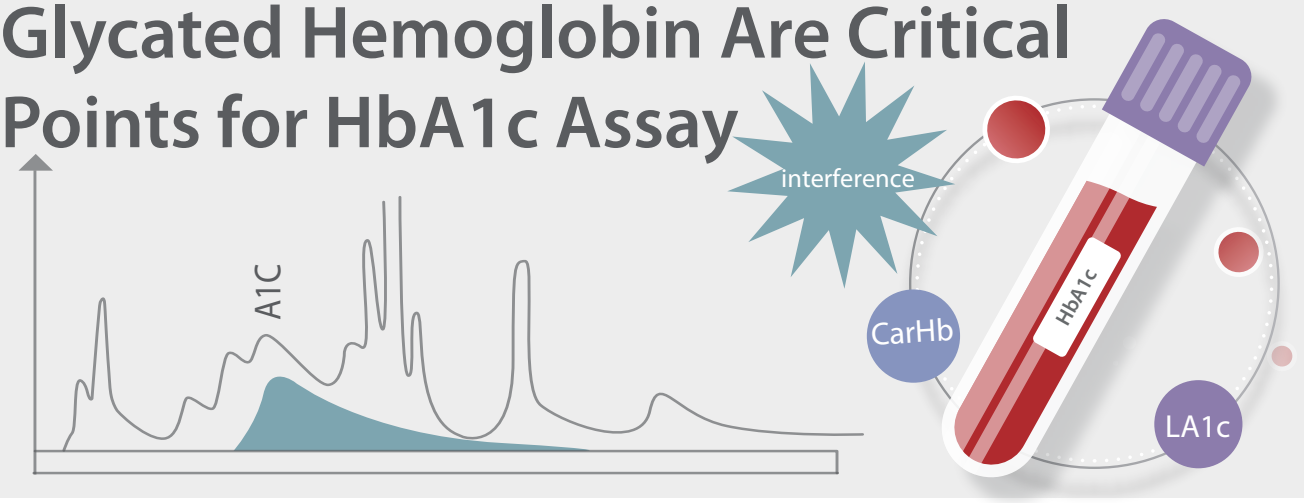
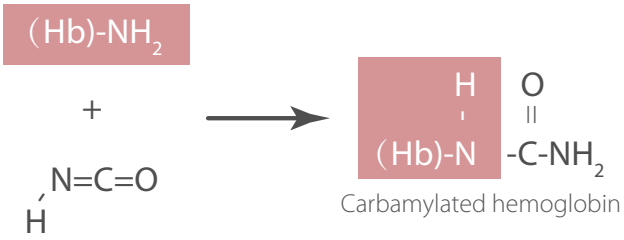
Carbamylated Hemoglobin and Labile Glycated Hemoglobin Are Critical Points for HbA1c Assay



Hemoglobin A1c (HbA1c) is a key analyte for monitoring the glycemic balance in diabetic patients, and is used for diabetes diagnosis in many countries. The potential interference of carbamylated hemoglobin (CarHb) and labile glycated hemoglobin (LA1c), can cause HbA1c results to be inaccurate. The effects vary depending on the specific HbA1c method used.

A Carbamylated hemoglobin

CarHb, which results from the binding of urea-derived isocyanic acid, is higher in patients with chronic kidney disease. [1]



CarHb formation is dependent on urea concentration and length of exposure to urea. [2]

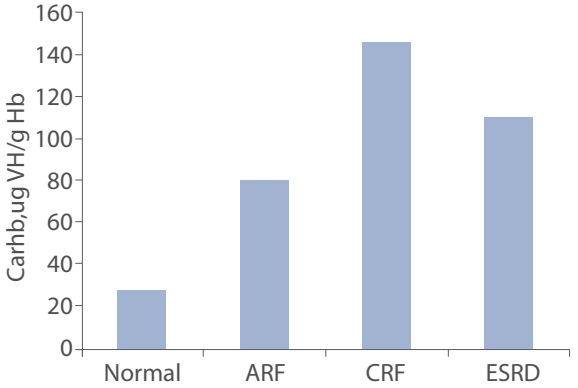


Fig.1. CarHb in acute renal failure (ARF), chronic renal failure (CRF), end-stage renal disease (ESRD), and normal subjects. Differences amongst groups were statistically significant by ANOVA. [2]

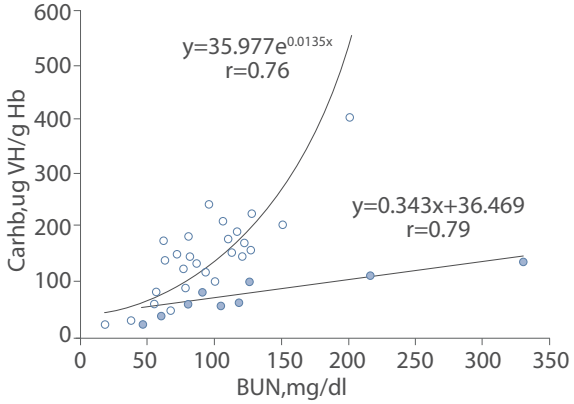


Fig.2.Carhb plotted against BUN level in patients with ARF (●) and CRF(○)

CarHb has a similar electric charge to HbA1c. When measured by ion-exchange high-performance liquid chromatography (HPLC), CarHb forms a peak which overlaps the peak of HbA1c, causing a falsely elevated HbA1c result. [3]

A 60-year-old man with underlying ischemic heart disease, hypertension, and type 2 diabetes mellitus was also treated for sepsis associated with an acute kidney injury. His Urea level was 91 mmol/l and creatinine level was 2.52 μmol/l. The HbA1c which was measured by HPLC HbA1c program was considered very high (21.9%), outside the reportable limit.

The HPLC chromatogram showed a very high carbamylated hemoglobin peak of 12.1% (Figure 3)pointing to the possibility of positive interference in the HbA1c measurement. [4]

Peak name	Retention time	Height	Area	Area(%)
A1a	0.2	16526	58905	1.9
A1b	0.28	34839	202876	6.6
LA1c/CHb-1	0.63	13038	95742	3.1
LA1c/CHb-2	0.8	22825	375871	12.1
A1c	0.99	18096	555061	21.9
P3	1.36	51313	351875	11.4
Ao	1.43	420664	1453418	47

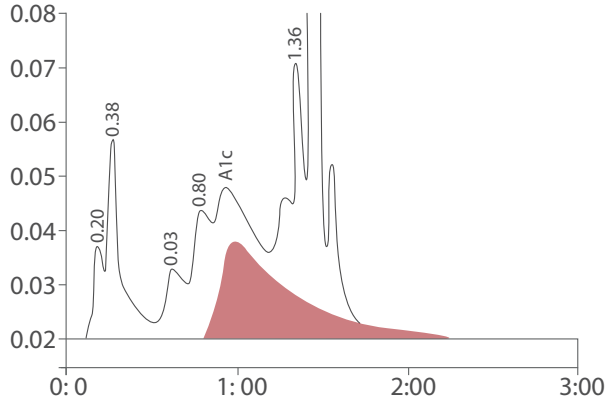


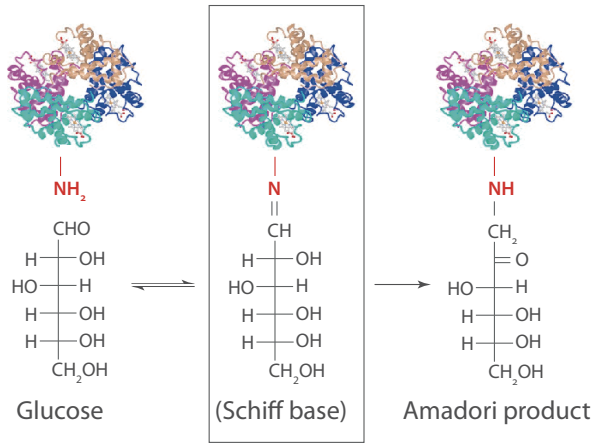
Fig.3.HPLC chromatogram for HbA1c analysis with high carbamylated Hb peak co-eluted with HbA1c (HbA1c peak highlighted in red)

Chronic renal failure develops in many diabetic patients. CarHb levels are even higher in chronic renal failure, and may represent a possible interference in HPLC during the HbA1c measurement.

So, HbA1c assay manufacturers should evaluate the anti-CarHb interference ability of HbA1c tests, and give clinical laboratories instructions.

Labile hemoglobin A1c

Labile hemoglobin A1c (LA1c, also known as pre-HbA1c or pre-glycohemoglobin), an unstable form, is a Schiff base formed during the non-enzymatic glycation of hemoglobin. The concentration of labile fraction varies with acute change in the plasma glucose level.



Labile hemoglobin A1c

LA1c potentially interferes in the estimation of HbA1c, causing a false low value, and may even hamper or delay the prompt treatment required for diabetics. This calls for a careful and detailed study of chromatograms for each sample.

The influence of increasing LA1c on HbA1c results was studied with in vitro glycation of samples by Aurore Desmons, etc. [1] The study shows that the increased LA1c peak led to a decrease of HbA1c values (Table 1).

Incubation time (min) with 0.25 mol/L glucose		0	15	17	22	27	30	45
Sample1	HbA_{1c}, mmol/mol	33	31	30	30	28	27	25
	HbA_{1c} %	5.2	5.0	4.9	4.9	4.7	4.6	4.4
	Peak recognized as(LA_{1c})%	1.2	3.1	3.4	4.0	4.5	4.8	6.3
Sample2	HbA_{1c}, mmol/mol	65	64	64	62	61	60	56
	HbA_{1c} %	8.1	8.0	8.0	7.8	7.7	7.6	7.3
	Peak recognized as(LA_{1c})%	1.3	3.1	3.1	4.0	4.6	4.8	6.2

Table 1. Interference of labile glycated hemoglobin (LA_{1C}) on HbA_{1C} measurements by Variant Ⅱ equipped with Dual kit program™

An article called "Labile Hemoglobin - A Biochemical Entity" concludes that LA1c should be noted carefully while estimating the HbA1c by HPLC technique as it is a potential source of

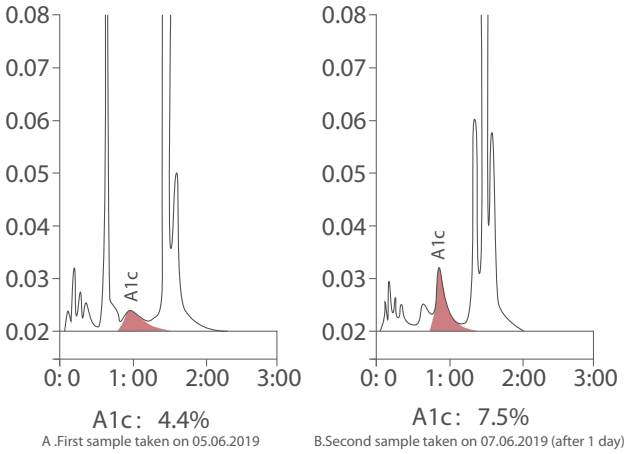


Fig. 4 .The chromatograms of the same sample run on 5/6/19 and 7/6/19

potential source of pre-analytical error.

The chromatogram for a patient with a diabetic history shows LA1c/CHb-1 and LA1c/ CHb-2 with a total area of10.7% and HbA1c with an area of 4.4% on 5/6/19. Finding a low value of HbA1c, the laboratory referred to the patient history and discovered that the patient had received treatment for high plasma glucose levels four days previously. As acute changes in the plasma glucose level can cause a high LA1c value, it was advised for the patient to test again after a gap of one day. On 7/6/19, the result of the repeat sample tested showed LA1c/CHb-1 with an area of only 1.9% and HbA1c with an area of 7.5%. [5]

Anti-Interference Study of CarHb and LA1c with Mindray Enzymatic HbA1c reagent

The aim of this study was to evaluate the influence of CarHb and LA1c on Mindray enzymatic HbA1c.

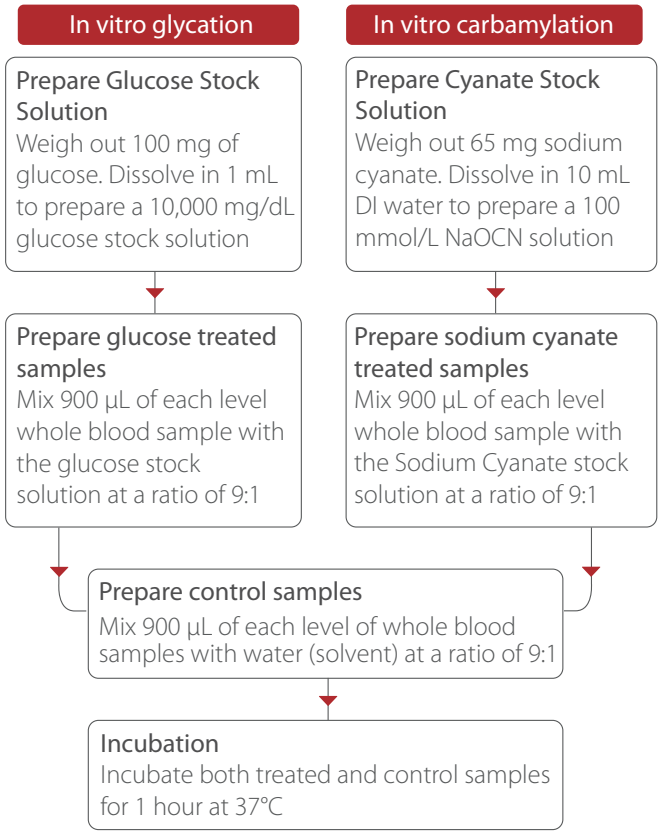


Fig.5. Procedures for in vitro carbamylation and glycation

Mindray R&D studied the influence of increasing in-vitro CarHb and LA1c concentration on HbA1c results with enzymatic chemistry method. The results can be seen in table 2.

Sample	Item	Sample 1				
		Repeat 1	Repeat 2	Repeat 3	Mean Value	Bias%
Whole blood control group	HbA1c%	6.67	6.65	6.71	6.68	/
Labile Hb		6.63	6.64	6.61	6.63	-0.7%
Carbamylated Hb		6.56	6.58	6.61	6.58	-1.4%

Sample	Item	Sample 2				
		Repeat 1	Repeat 2	Repeat 3	Mean Value	Bias%
Whole blood control group	HbA1c%	9.40	9.42	9.37	9.40	/
Labile Hb		9.35	9.39	9.37	9.37	-0.3%
Carbamylated Hb		9.28	9.30	9.24	9.28	-1.3%

Table 2. Interference of CarHb and LA1c on HbA1c measured by Mindray enzymatic method

All relative bias, compared with control group in table 2, is less than 2%, which proves there is no significant inter ference from CarHb and LA1c by the chemistry enzymatic method.

Conclusion

HbA1c is not affected by blood sugar levels alone, it can also be affected by chemical modifications of Hb. CarHb and LA1c remain critical issues in chromatography-based HbA1c assay. Misleading interpretation can lead to a wrong estimation of glycemic control and misdiagnosis. It is therefore prudent to rule out such confounding factors before making a therapeutic decision.

Therefore, when a suspicious HbA1c value occurs, further investigations should be performed. Measurement of HbA1c with a different assay method, or testing serum fructosamine and continuous glucose to monitor patient's glucose control are suggested.

Mindray enzymatic HbA1c shows no significant interference from Hb derivatives (CarHb and LA1c). It is concluded to be beneficial for patients who have kidney disease and diabetes mellitus as well as patients who have an acute change in glucose level (such as those who have had a blood transfusion).

References

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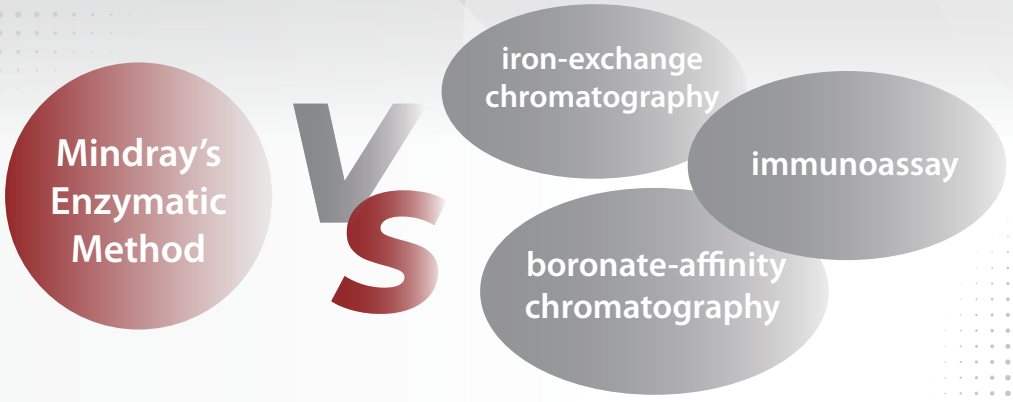
Method Comparison Study of Mindray's Enzymatic HbA1c Assay



HbA1c is the cornerstone of diabetes care. It is widely used as a treatment goal as well as to predict the risk of complications developing in diabetes mellitus patients.

There are many analytical methods used in measuring HbA1c. The heterogeneity of methodology which is generated concerns the comparability and usability of HbA1c. In order to obtain comparable results of HbA1c by different methods, the standardization of these methods is essential.

Commercial Methods of HbA1c Measurement

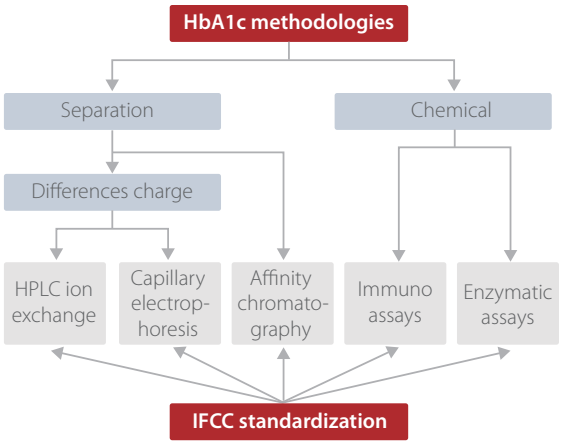


Fig.1.Analytical concepts of HbAlc measurement methods and their traceability to the IFCC-RMP

There are two major analytical concepts: one is based on the separation of Hb fractions, and the other is based on chemical reactions (Fig.1). Although different analytes are measured by these methods, assays can be standardized according to the Reference Measurement Procedure (RMP) of the International Federation of Clinical Chemistry (IFCC)[1] .

Global Standardization of HbA1c Measurement

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Working Group on the Standardization of HbA1c has established an international reference measurement system for HbA1c. Glycated and non-glycated N-terminal hexapeptides are separated by reversed phase high-performance liquid chromatography (HPLC) followed by identification and quantification by capillary electrophoresis (CE) or electrospray ionization mass spectrometry (ESI-MS).

The successful preparation of pure HbA1c calibration material should lead to further improvements in inter-method and inter-laboratory variability.

In 2007, a meeting was held in Milan, and a consensus statement was published jointly by American Diabetes Association (ADA), European Association for the Study of Diabetes (EASD), IFCC and International Diabetes Federation (IDF)[2]. Their recommendations were:

"HbA1c test results should be standardized worldwide, including the reference system and results reporting. The new IFCC reference system for HbA1c represents the only valid anchor to implement standardization of the measurement. HbA1c results are to be reported worldwide in IFCC units (mmol/mol) and derived NGSP units (%), using the IFCC-NGSP master equation."

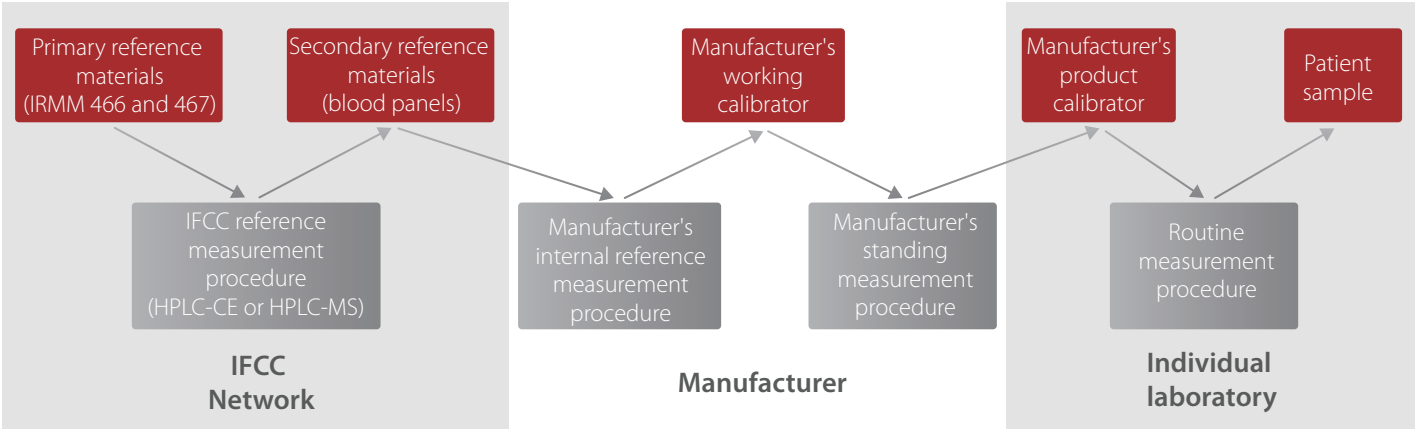
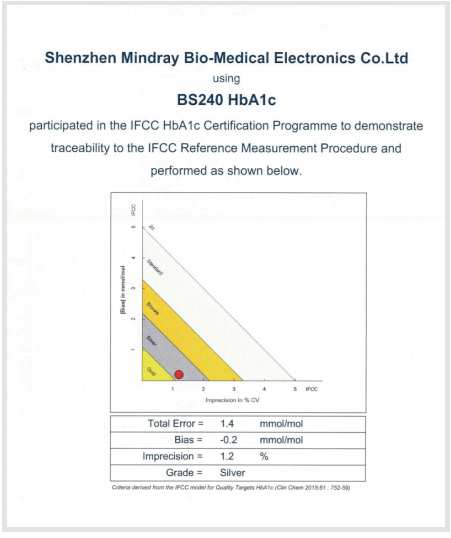
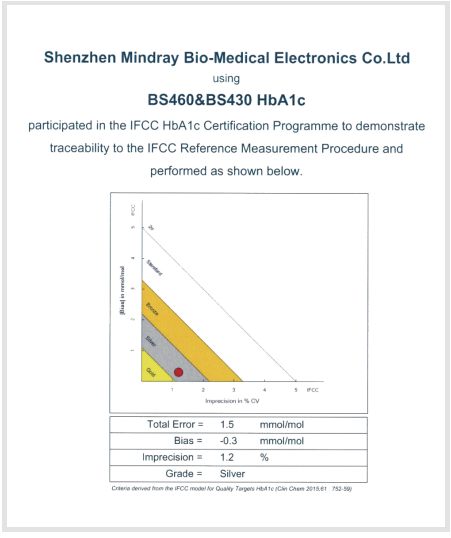


Fig.2 IFCC reference measurement system and traceability chain for HbA1c

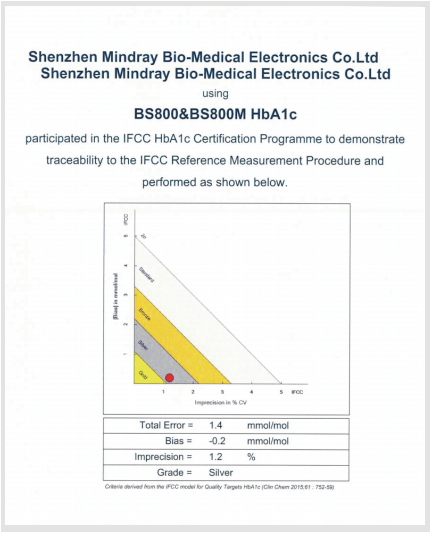
Mindray's enzymatic HbA1c can be traceable to the IFCC reference standard, and has high accuracy with small bias and low CV%, helping doctors to provide better diabetes diagnosis and management.


Shenzhen Mindray Bio-Medical Electronics Co.Ltd
using
BS240 HbA1c
participated in the IFCC HbA1c Certification Programme to demonstrate traceability to the IFCC Reference Measurement Procedure and performed as shown below.

Total Error =	1.4	mmol/mol
Bias =	-0.2	mmol/mol
Imprecision =	1.2	%
Grade =	Silver	


Shenzhen Mindray Bio-Medical Electronics Co.Ltd
using
BS460&BS430 HbA1c
participated in the IFCC HbA1c Certification Programme to demonstrate traceability to the IFCC Reference Measurement Procedure and performed as shown below.

Total Error =	1.5	mmol/mol
Bias =	-0.3	mmol/mol
Imprecision =	1.2	%
Grade =	Silver	


Shenzhen Mindray Bio-Medical Electronics Co.Ltd
Shenzhen Mindray Bio-Medical Electronics Co.Ltd
using
BS800&BS800M HbA1c
participated in the IFCC HbA1c Certification Programme to demonstrate traceability to the IFCC Reference Measurement Procedure and performed as shown below.

Total Error =	1.4	mmol/mol
Bias =	-0.2	mmol/mol
Imprecision =	1.2	%
Grade =	Silver	

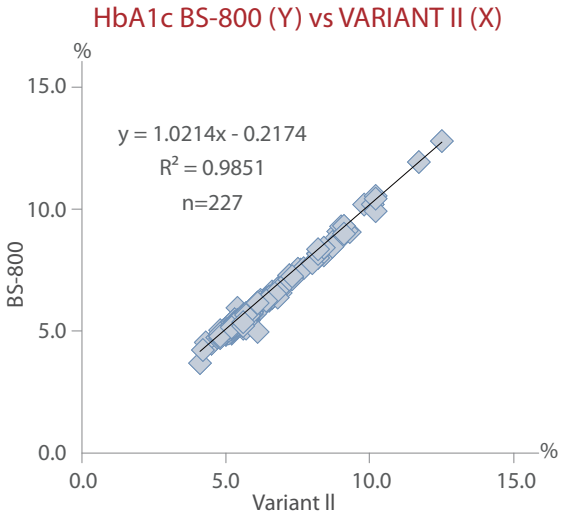
Fig3. Mindray HbA1c IFCC Certificates

Method Comparisons among Commercialized Methods

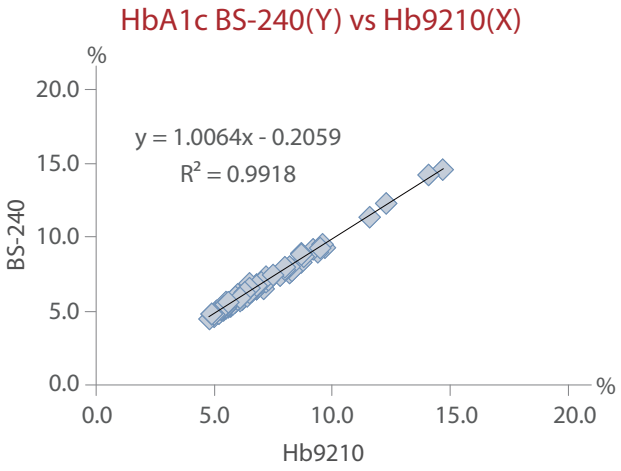
Mindray R&D compared its enzymatic HbA1c method with other available laboratory methods. The assay principles of these other methods, from Bio-Rad, Trinity Biotech and Roche, use iron-exchange chromatography, boronate-affinity chromatography and immunoassay respectively.

All methods can be traceable to the IFCC Reference Method.

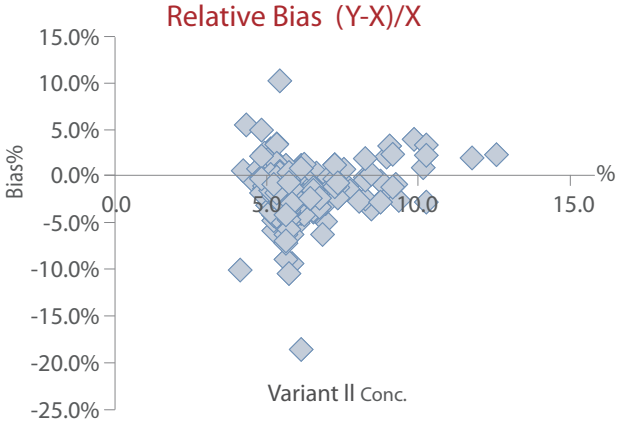
Every sample was tested in duplicate. Each method was calibrated according to the manufacturer's instructions and two control materials, including normal and high levels, were tested as internal quality control. HbA1c results were reported as a percentage of the total hemoglobin. Correlation, regression and relative bias analysis are shown in Fig.4, Fig.5 and Fig.6.



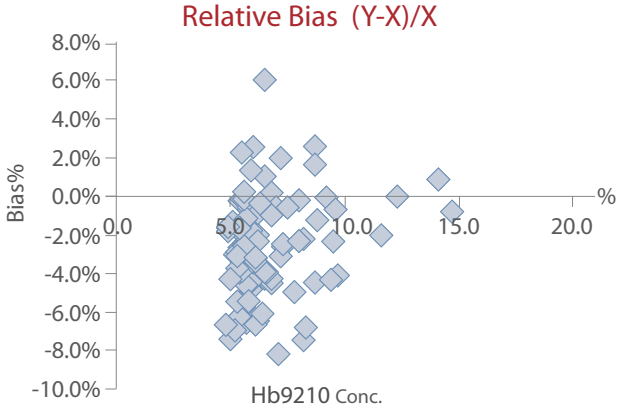
(a)Correlation between HbA1c results obtained by BS-800 and Variant Ⅱ



(a)Correlation between HbA1c results obtained by BS-240 and Hb9210



(b)Relative Bias%=(Y-X)/X
Y is HbA1c results obtained by BS-800;
X is HbA1c results obtained by Variant Ⅱ.



(b)Relative Bias%=(Y-X)/X
Y is HbA1c results obtained by BS-240;
X is HbA1c results obtained by Hb9210.

BS-800 VS Variant II											
Total Sample number		Min Con.		Max Con.		Slope		Intercept		R^2	
227		3.7		12.8		1.021		-0.217		0.985	
						Pass				Pass	
Level1 Conc	6.5	Level2 Conc	7	Level3 Conc	8	Level4 Conc	8.5	Level5 Conc	9		
Rel. Bias	Abs Bias	Rel. Bias	Abs Bias	Rel. Bias	Abs Bias	Rel. Bias	Abs Bias	Rel. Bias	Abs Bias		
-1.2%	-0.1	-1.0%	-0.1	-0.6%	0.0	-0.4%	0.0	-0.3%	0.0		
Pass		Pass		Pass		Pass		Pass			

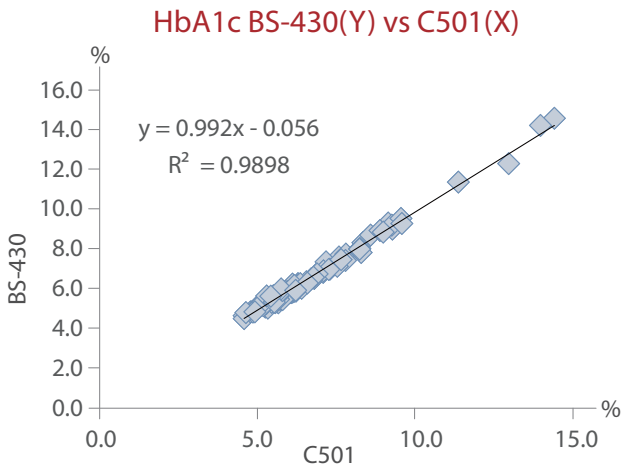
(c) Parameters of regression line and relative bias data at key HbA1c levels

Fig.4 Method comparison between Mindray BS-800 (Biochemistry enzymatic method) and Bio-Rad Varian Ⅱ (iron-exchange chromatography method)

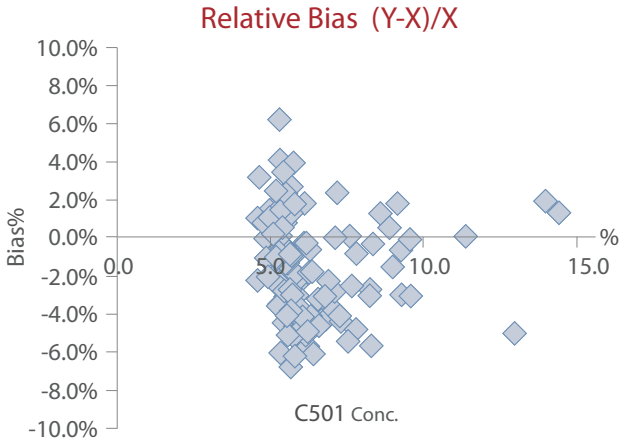
BS-240 VS Hb9210											
Total Sample number		Min Con.		Max Con.		Slope		Intercept		R^2	
120		4.5		14.6		1.006		-0.206		0.992	
						Pass		/		Pass	
Level1 Conc	6.5	Level2 Conc	7	Level3 Conc	8	Level4 Conc	8.5	Level5 Conc	9		
Rel. Bias	Abs Bias	Rel. Bias	Abs Bias	Rel. Bias	Abs Bias	Rel. Bias	Abs Bias	Rel. Bias	Abs Bias		
-2.5%	-0.2	-2.3%	-0.2	-1.9%	-0.2	-1.8%	-0.2	-1.6%	-0.1		
Pass		Pass		Pass		Pass		Pass			

(c) Parameters of regression line and relative bias data at key HbA1c levels

Fig.5 Method comparison between Mindray BS-240 (Biochemistry enzymatic method) and Trinity Biotech Premier Hb9210 (boronate-affinity chromatography method)



(a)Correlation between HbA1c results obtained by BS-240 and Hb9210



(b)Relative Bias%=(Y-X)/X
Y is HbA1c results obtained by BS-430;
X is HbA1c results obtained by C501.

BS-800 VS Variant II											
Total Sample number		Min Con.		Max Con.		Slope		Intercept		R^2	
120		4.5		14.6		0.992		-0.056		0.990	
						Pass				Pass	
Level1 Conc	6.5	Level2 Conc	7	Level3 Conc	8	Level4 Conc	8.5	Level5 Conc	9		
Rel. Bias	Abs Bias	Rel. Bias	Abs Bias	Rel. Bias	Abs Bias	Rel. Bias	Abs Bias	Rel. Bias	Abs Bias		
-1.7%	-0.1	-1.6%	-0.1	-1.5%	-0.1	-1.5%	-0.1	-1.4%	-0.1		
Pass		Pass		Pass		Pass		Pass			

(c) Parameters of regression line and relative bias data at key HbA1c levels

Fig.6 Method comparison between Mindray BS-430 (Biochemistry enzymatic method) and Roche Cobas C501 (immunoassay method)

According to the HbA1c method comparison criteria from 2019 CLIA [3]and 2020 CAP [4], Mindray's enzymatic HbA1c method showed good correlations (R2>0.96) with Bio-Rad Variant II HPLC (ion-exchange chromatography), Trinity Hb9210 HPLC (boronate affinity) and Roche C501 (immunoturbidimetry). The relative bias% at key HbA1c levels between each of the two methods is less than 5%.

ITEM	Report Unit	2019 CLIA &2020 CAP		
		Slope (k)	R^2	Relative Bias%
HbA1c	%	1±0.05	≥0.95	±5.00%

Table 1. HbA1c method comparison criteria

Conclusion

The global standardization of HbA1c measurement makes HbA1c results obtained from different methods more accurate and comparable.

Mindray enzymatic HbA1c is well in line with other commercialized testing methods. It has proven to be a reliable and effective method for the quantitative determination of HbA1c.

References

[1] HbA1c: A Review of Analytical and Clinical Aspects. Ann Lab Med 2013; 33:393-400.

[2] Consensus statement on the worldwide standardization of the hemoglobin A1C measurement: the American Diabetes Association, European Association for the Study of Diabetes, International Federation of Clinical Chemistry and Laboratory Medicine, and the International Diabetes Federation. Diabetes Care. 2007 Sep;30(9):2399-400. doi: 10.2337/dc07-9925.

[3] 2019: CLIA proposed changes to PT acceptable limits

[4] CAP (College of American Pathologists) acceptable limit for grading of the target value in 2020

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