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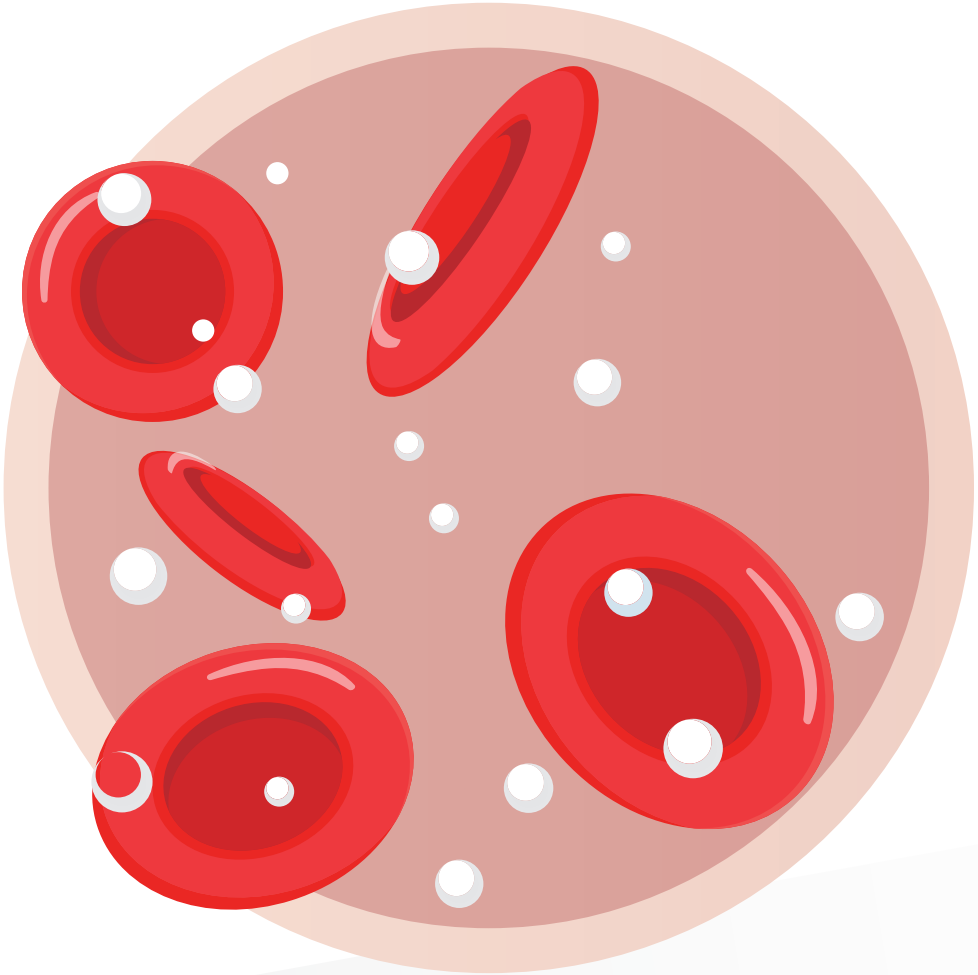
ChemBook

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



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Content

D ab M (DM) a ba a c a . O
11 ad (20-79 a) d a DM b
I a a D ab F d a (IDF) 2019, a d
a c c a a d

O c d a d, a a c a , c a
c a , d ca , a d/ . R a d
a d, c c a ca

HbA1c a d a a a c c
c . E a d c HbA1c ca ca
d c DM- a d b d a d a .
T c a 6
-c d a , a d 3
-c d a , a a a
c a a c . [6]

S c HbA1c a a a d 1958, a d
a d b a ab d a a d
DM. A a c a c d d b
d , HbA1c a c a
a c , c a ab a
c c a a a , a d c ab d c
a c ca d c .

1 IDF DIABE E A LA 2019. :// . . / /

2 , K. & L , M. D M : D . D M 93, 7 (2016).

3 A D A . C , D D : M C D 2020. D C 43, 14 (2020).

4 G AJ, A MJ, B JI, . C A A C E A C E 2 2017 . E 2017; 23(1): 207-38.

5 A D A . G : M C D 2020. D C 43, 66 76 (2020).

6 H A1 F : A C E G I . ( ): C A D H ; 2014 26.

7 K D G : I - 2 (K D 33). L 352: 837 853, 1998

8 IM, . A 2 (K D 35): . BMJ 321:405 412, 2000

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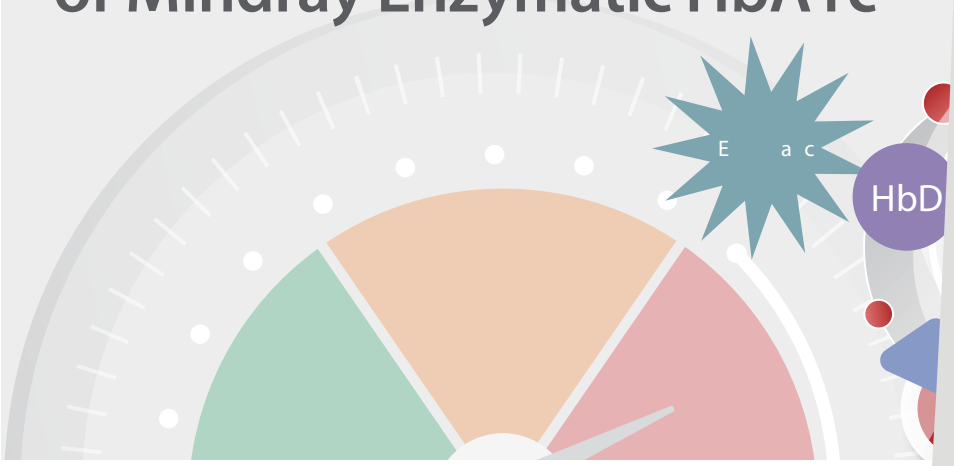
The Anti-interference Capacity of Mindray Enzymatic HbA1c



HbA1c, a a d 1958, a b c c d ab c , d a a d a c . R c d a a da d c ca ac c , a a ad a a , c a b - a , a , a d ab c c c c a d 3-4 .

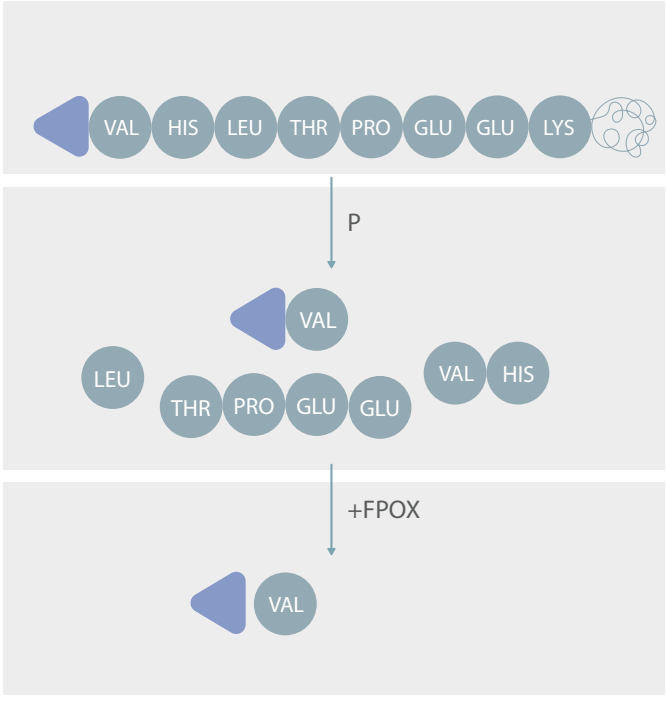
Interference Caused by Hemoglobin Variants

T IFCC a d d HbA1c a Hb c a b b ca d a b N- a a b a-c a .[1] T c b a a , c a HbS, HbC, HbE a d HbD, a a ac d b b a-c a . T a , ac b a a , d d d d, a ca a acc a HbA1c b ca a a c c . A a , a HbA1c a a c ca ad b ca b c a ab a c a a b ca d.

D b C H b V T a a

A a d HbA1c, M d a B c a c a a c db ca c a d ca ad a a .O c ad a a a - c ca ac a a b a a .

F a c d, b d a a da d b c d cd .T c a a acd, c ca ca dN- a a acd b b a-c a .T a d c db ca dN- a a acd a b c c ac d ca c a HbA1c. T d a c da a ca b c Hb a a .[4]



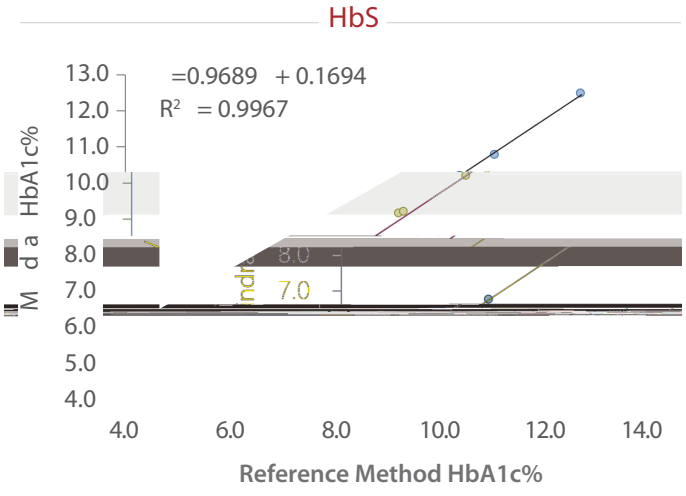
G c A acd

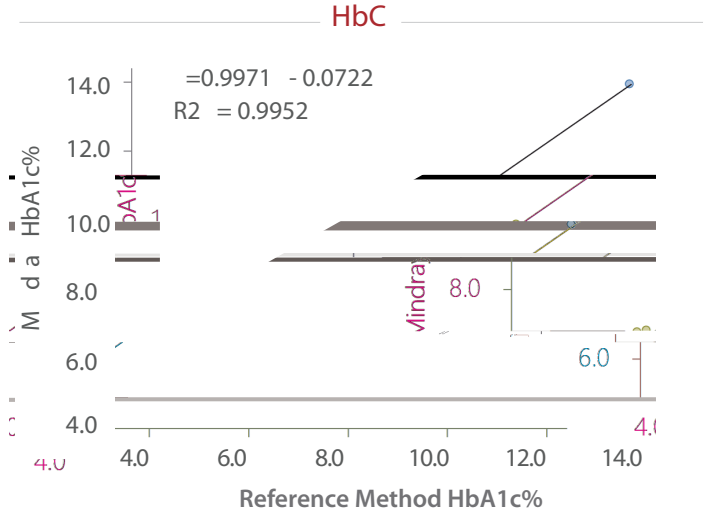
E a cA a HbA1c M a

Mindray Enzymatic HbA1c Anti-interference Capacity

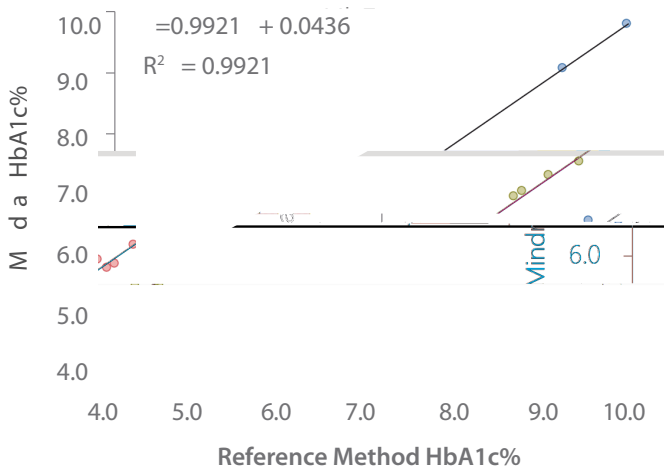
T a a - c ca ac , a d da a d .Sa c c d Q B a M d ca C T N a d , c E a R c Lab a G c b , a d P a R c Lab a HbA1c a da d a .T a HbA1c a db a IFCC ca b a da c a a .T c a HbS, HbC, HbE, a d HbD a db ca a c a d - c a d HPLC. HbA1c (NGSP%) a a d BS-800M c a a .N ca c b a (. ., a a 5.0%) a b d HbS, HbC, HbE a d HbD. T da a db M d a d a a a db E a P a R c Lab a a a da d d ab a dc a :

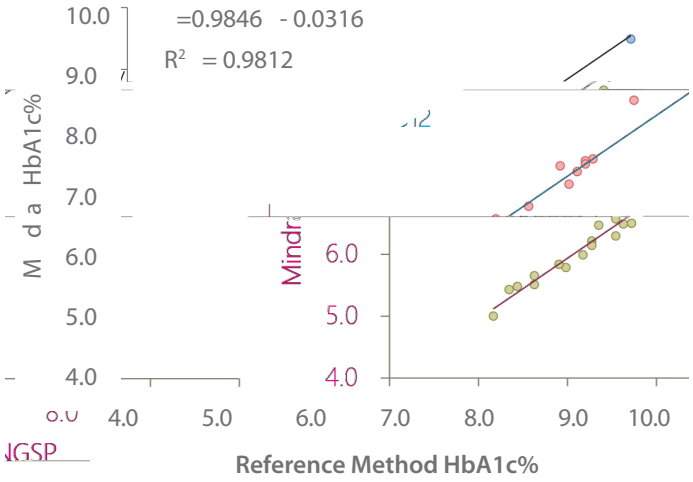
Variants	N	Range (%Va a)	Range (%HbA1c)	Relative Bias (Ra B a)	
				6%HbA1c	9%HbA1c
HbS	20	33 42%	4.9 12.7%	-0.2% (-3.2% 4.9%)	-0.1% (-0.2% 0.4%)
HbC	20	28 97%	4.6 14.0%	-1.8% (-4.3% 1.9%)	-2.8% (-5.0% -0.6%)
HbE	25	19 94%	4.9 9.8%	-0.4% (-2.3% 3.4%)	-0.5% (-0.5% -0.4%)
HbD	25	38 42%	5.2 9.7%	-1.2% (-3.3%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





HbE





Summary

A ac a c d d b d , HbA1c a ca c , d a , a d d ab . Hb a a , c a c a a d d (HbS, HbC, HbE, a d HbD), ca HbA1c . T a c d M d a BS c ca c a d c a a .

R c

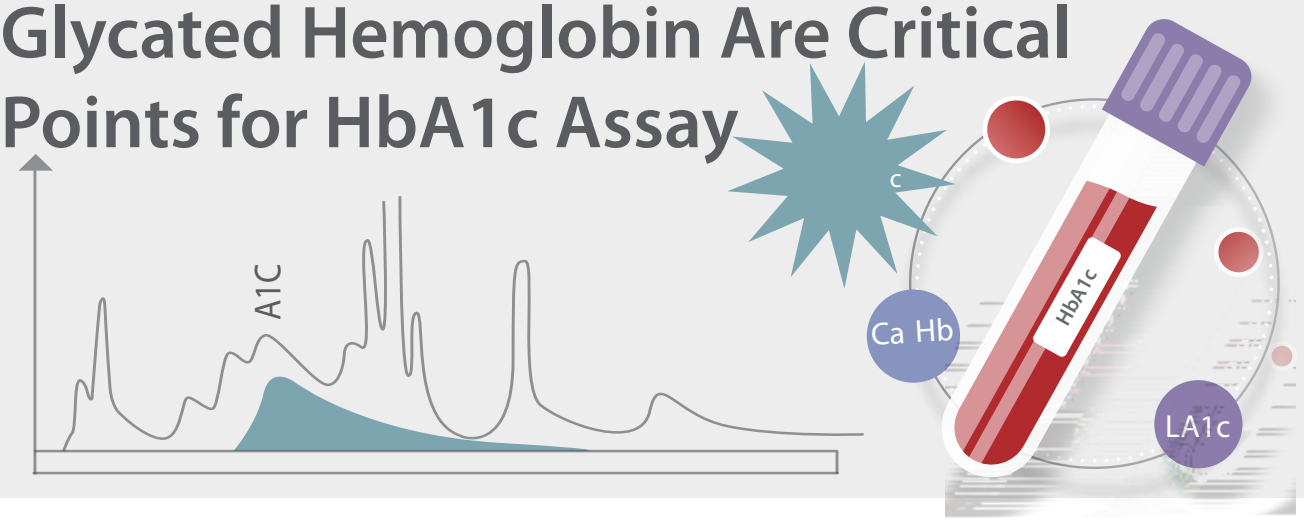
1 √G : IFCC

2 E , . L., M , √J. & C , H. J. H M . B 5, 2043 2052 (2013).

3 E √: H -

4 , J. M. & M , . C H A1 M I . A J C 141, 5 16 (2014).

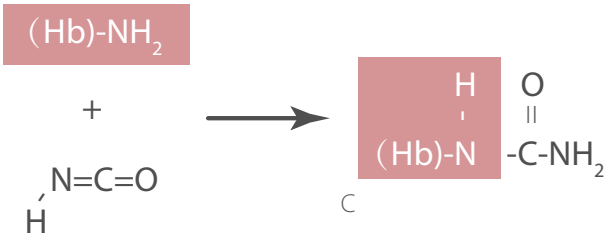
Carbamylated Hemoglobin and Labile Glycated Hemoglobin Are Critical Points for HbA1c Assay



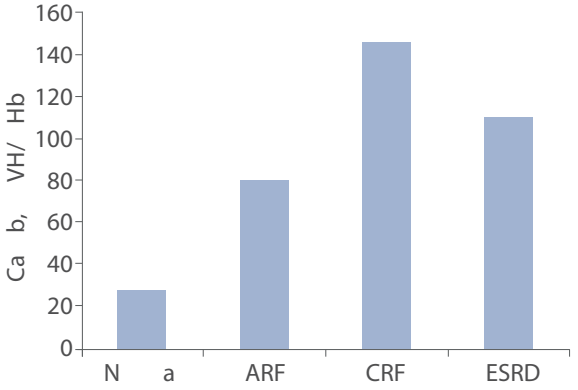
H b A1c (HbA1c) a a a c c ba a c d ab c a , a d d d ab d a a c .T a c ca ba a d b (Ca Hb) a d ab ca d b (LA1c), ca ca HbA1c b acc a .T c a d d c c HbA1c d d.

A Carbamylated hemoglobin

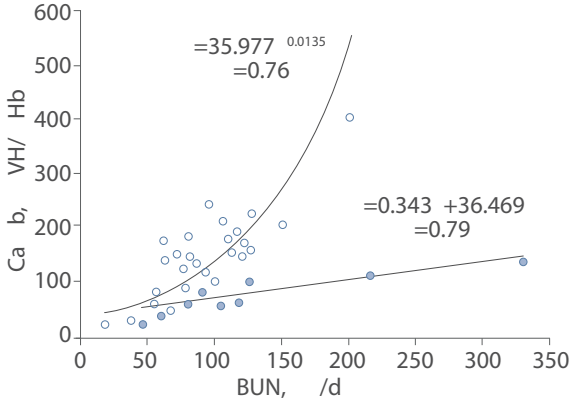
Ca Hb, c b d a-d d c a c ac d, a c c d d a .[1]



Ca Hb a d d ac c a a d a.[2]



F .1. Ca Hb ac a a (ARF), c c a a (CRF), d- a a d a (ESRD), a d a b c . D c a a ca ca b ANOVA.[2]



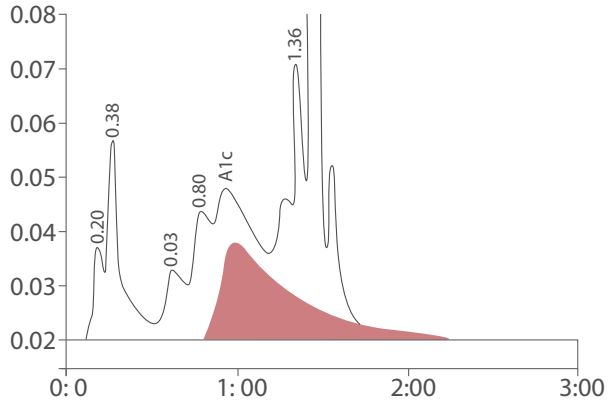
F .2.Ca b d a a BUN a ARF (●) a d CRF(○)

Ca Hb a a a c cc a HbA1c. W a d b - c a - a c d c a a (HPLC), Ca Hb a a c a a HbA1c, ca a a a d HbA1c .[3]

A 60- a - d a d c c a d a , , a d 2 d ab a a a d a ca d a ac d . H U a a 91 / a d c a a 2.52 / . T HbA1c c a a d b HPLC HbA1c a a c d d (21.9%), d ab .

T HPLC c a a d a ca ba a d b a 12.1% (F 3) b c HbA1c a .[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
A	1.43	420664	1453418	47



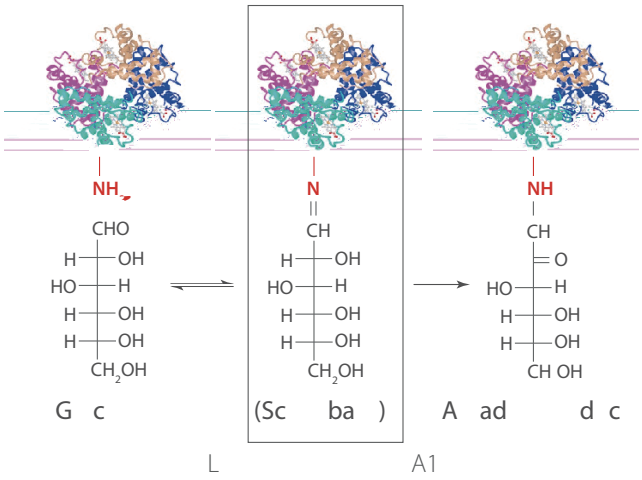
F .3.HPLC c a a HbA1c a a ca ba a - d Hb a c - d HbA1c (HbA1c a d d)

C c a a d a d ab c a . Ca Hb a c c a a , a d a a b c HPLC d HbA1c a .

S , HbA1c a a a ac d a a a -Ca Hb c ab HbA1c , a d c ca ab a c .

Labile hemoglobin A1c

Lab b A1c (LA1c, a a -HbA1c - c b), a ab , a Sc ba d d - a c ca b . T c c a ab ac a ac c a a a c .



G c (Sc ba) A ad d c

L A1

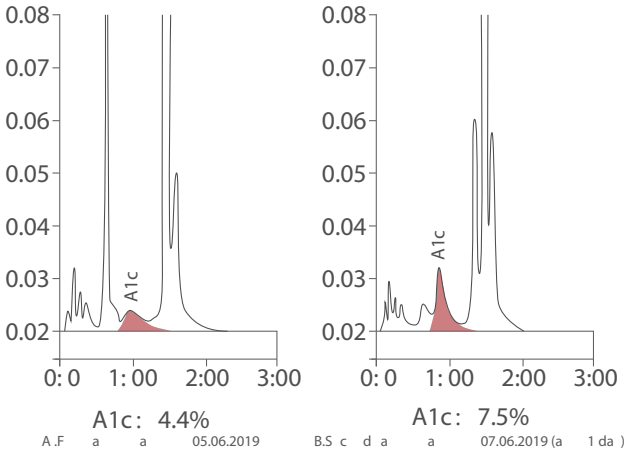
LA1c a a HbA1c, ca a a a , a d a a d d ab c . T ca a ca a dd a d d c a a ac a .

T c c a LA1c HbA1c a d d ca a b A D , c. [1] T d a c a d LA1c a d a d c a HbA1c a (Tab 1).

Incubation time (min) with 0.25 mol/L glucose		0	15	17	22	27	30	45
Sa 1	HbA_{1c}, /	33	31	30	30	28	27	25
	HbA_{1c} %	5.2	5.0	4.9	4.9	4.7	4.6	4.4
	P a c d a (LA_{1c}) %	1.2	3.1	3.4	4.0	4.5	4.8	6.3
Sa 2	HbA_{1c}, /	65	64	64	62	61	60	56
	HbA_{1c} %	8.1	8.0	8.0	7.8	7.7	7.6	7.3
	P a c d a (LA_{1c}) %	1.3	3.1	3.1	4.0	4.6	4.8	6.2

Tab 1. I c ab ca d b (LA_{1c}) HbA_{1c} a b Va a Ⅱ d D a a ™

A a c ca d Lab H b - A B c ca E c c d a LA1c d b d ca a HbA1c b HPLC c a a a c



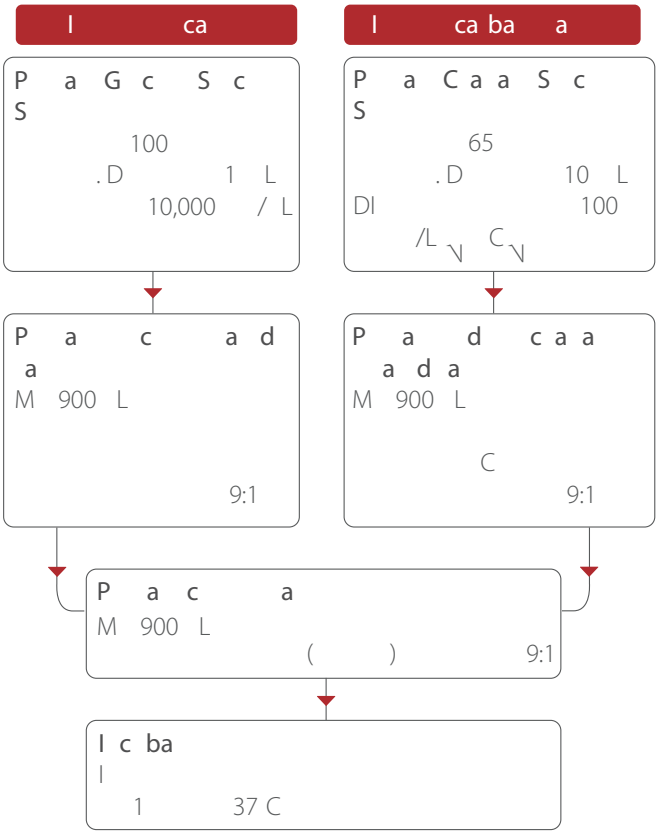
F .4.T c a a a a 5/6/19 a d 7/6/19

a c -a a ca .

T c a a a a a d ab c LA1c/CHb-1 a d LA1c/ CHb-2 a a a a 10.7% a d HbA1c a a a 4.4% 5/6/19. F d a a HbA1c, ab a d a a d d c d a a ad c d a a a c da . A ac c a a a c ca ca a LA1c a , a ad d a a a a a a da . O 7/6/19, a a d d LA1c/CHb-1 a a a 1.9% a d HbA1c a a a 7.5%. [5]

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

T a d a a a c Ca Hb a d LA1c M d a a c HbA1c.



F .5. P c d ca ba a a d ca

M d a R&D d d c c a - Ca Hb a d LA1c c c a HbA1c a c c d. T ca b ab 2.

Sample	Item	Sample 1				
		Repeat 1	Repeat 2	Repeat 3	Mean Value	Bias%
W b d c	HbA1c%	6.67	6.65	6.71	6.68	/
Lab Hb		6.63	6.64	6.61	6.63	-0.7%
Ca ba a d Hb		6.56	6.58	6.61	6.58	-1.4%

Sample	Item	Sample 2				
		Repeat 1	Repeat 2	Repeat 3	Mean Value	Bias%
W b d c	HbA1c%	9.40	9.42	9.37	9.40	/
Lab Hb		9.35	9.39	9.37	9.37	-0.3%
Ca ba a d Hb		9.28	9.30	9.24	9.28	-1.3%

Tab 2. I c Ca Hb a d LA1c HbA1c a d b M d a a c d

A a b a , c a d c ab 2, a a a a a ac c a a 2%, c ca c c (c a a ad a b d Ca Hb a d LA1c b c a c d. a).

Conclusion

HbA1c a c d b b d a a , ca a b a c d b c ca d ca Hb. Ca Hb a d LA1c a c ca c a a -ba d HbA1c a a . M ad a ca ad a a c c c a d d a . I d c c d ac b a a a cd c .

T , a c HbA1c a cc , a d b d. M a HbA1c a d a a d, c a a d c c a ' c c a d.

M d a a c HbA1c ca c Hb d a (Ca Hb a d LA1c). I c c d d b b c a a a d d a a d d ab

R c

1 L H A1 . B M 2017;27(2):378 86.

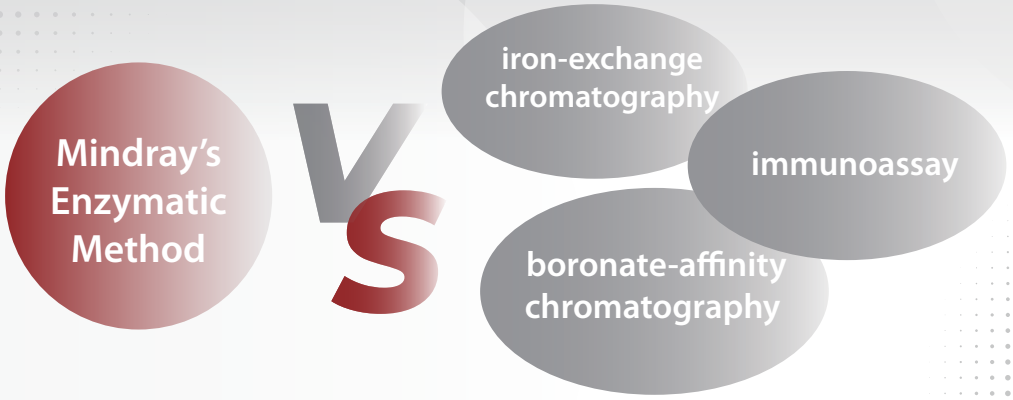
2 F . K I , L 48 (1995), . 1605 1610.

3 L H A(1) . B . 2017; 27(2): 378-86.

4 H : . J B M L . 2021; 57: 1-5.

5 L H - A B E . J AL F CLI JCAL A D E E IME AL I E IGA I . 11. 1.M 2020 . 00732.

Method Comparison Study of Mindray's Enzymatic HbA1c Assay

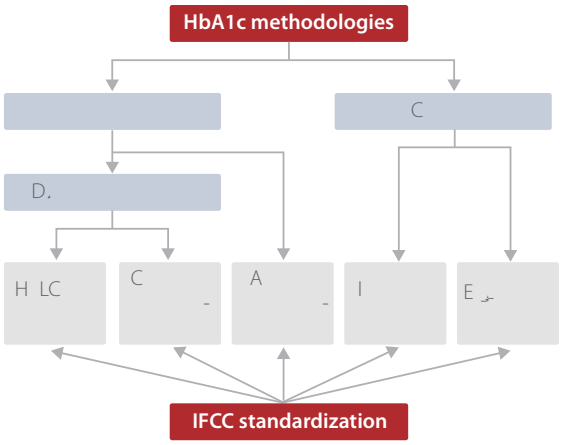


HbA1c c d ab ca . I d d a a a a a d c c ca d d ab a .

T a a a a ca d d a HbA1c. T d c a d c c c a ab a d ab HbA1c. I d b a c a ab HbA1c b d d , a da d a d a .

T a a a a ca c c : ba d a a Hb ac , a d ba d c ca ac (F .1). A d a a a a d b d , a a ca b a da d d acc d R c M a P c d (RMP) I a a F d a C ca C (IFCC)[1].

Commercial Methods of HbA1c Measurement



F .1.A a ca c c HbA c a d a d ac ab FCC-RMP

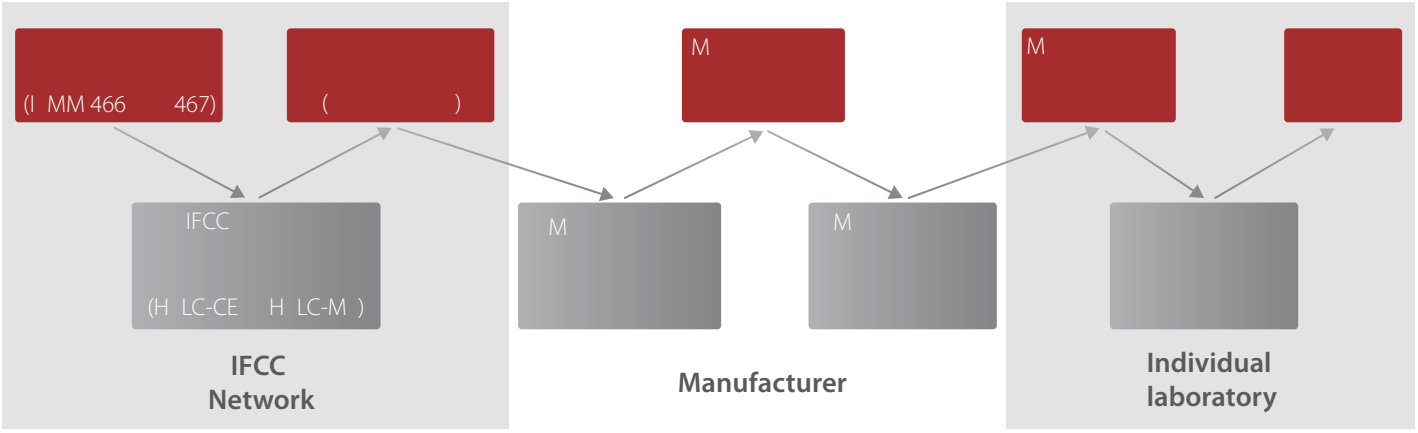
Global Standardization of HbA1c Measurement

T I a a F d a C ca C a d Lab a M d c (IFCC) W G S a da d a HbA1c a ab d a a a c a HbA1c. G ca d a d - ca d N- a a d a a a d b d a - a c d c a a (HPLC) d b d ca a d a ca b ca a c (CE) c a a a c (ESI-MS).

T cc a a HbA1c ca b a a a d ad - d a d - ab a a ab .

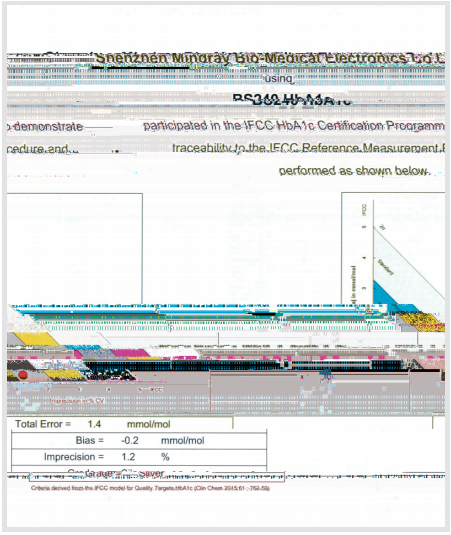
I 2007, a a d M a , a d a c a a b d b A ca D ab A c a (ADA), E a A c a S d D ab (EASD), IFCC a d I a a D ab F d a (IDF)[2]. T c da :

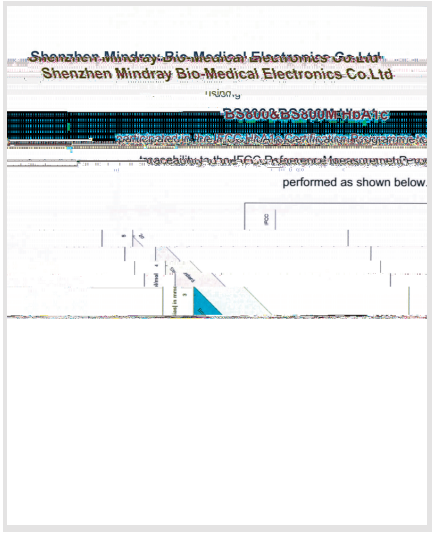
"HbA1c test results should be standardized worldwide, including the reference system and results reporting. The new IFCC reference system for HbA1c represents the only valid anchor to implement standardization of the measurement. HbA1c results are to be reported worldwide in IFCC units (mmol/mol) and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



F .2 IFCC c a a d ac ab c a HbA1c

M d a ' a c HbA1c ca b ac ab IFCC c a da d, a d a acc ac a b a a d CV%, d c d b d ab d a a d a a .





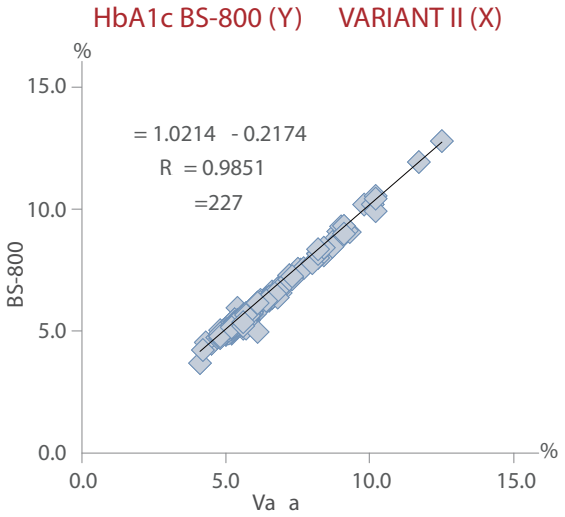
F 3. M d a HbA1c IFCC C ca

Method Comparisons among Commercialized Methods

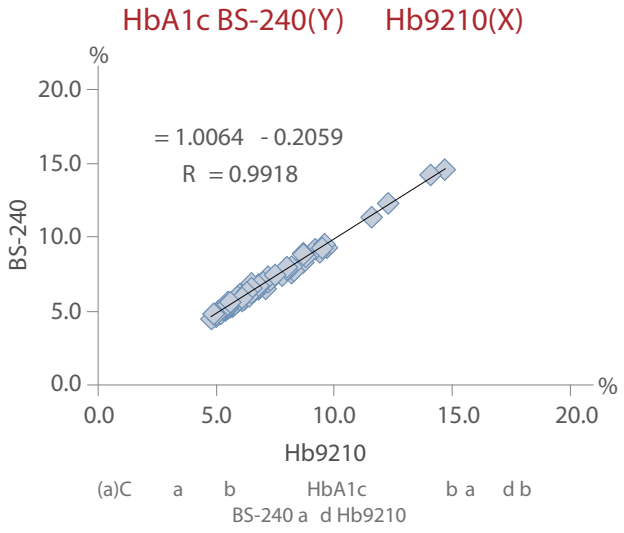
M d a R&D c a d a c HbA1c d a a ab ab a d . T a a c d, B -Rad, T B c a d R c , - c a c a a , b a -a c a a a d a a c .

A d ca b ac ab IFCC R c M d.

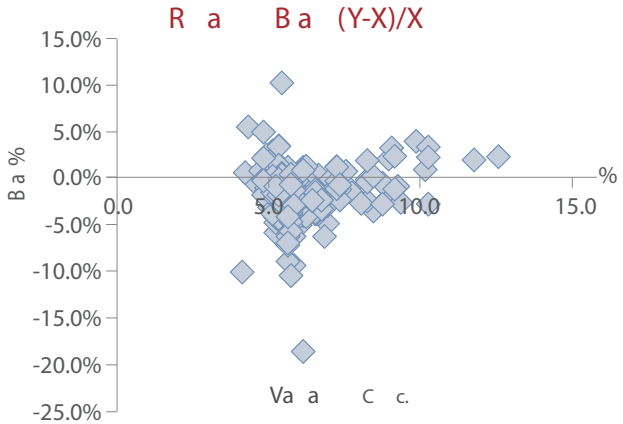
E a a d d ca . Eac d a ca b a d acc d a ac ' c a d c a a , c d a a d , d a a a c . HbA1c d a a c a a b . C a , a d a b a a a a F .4, F .5 a d F .6.



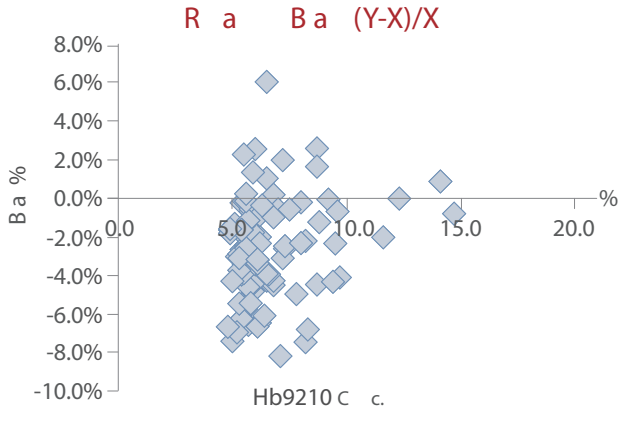
(a)C a b HbA1c b a d b BS-800 a d Va a Ⅱ



(a)C a b HbA1c b a d b BS-240 a d Hb9210



(b)R a B a %=(Y-X)/X Y HbA1c b a d b BS-800; X HbA1c b a d b Va a Ⅱ.



(b)R a B a %=(Y-X)/X Y HbA1c b a d b BS-240; X HbA1c b a d b Hb9210.

BS-800 VS Variant II

T a Sa b	M C .	Ma C .	S	I c	R^2
227	3.7	12.8	1.021	-0.217	0.985
			Pa		Pa

L 1 C c	6.5	L 2 C c	7	L 3 C c	8	L 4 C c	8.5	L 5 C c	9
R . Ba	Ab Ba	R . Ba	Ab Ba	R . Ba	Ab Ba	R . Ba	Ab Ba	R . Ba	Ab Ba
-1.2%	-0.1	-1.0%	-0.1	-0.6%	0.0	-0.4%	0.0	-0.3%	0.0
Pa		Pa		Pa		Pa		Pa	

(c) Pa a a d a b a da a a HbA1c

F .4 M d c a b M d a BS-800 (B c a c d) a d B -Rad Va a Ⅱ (- c a c a a d)

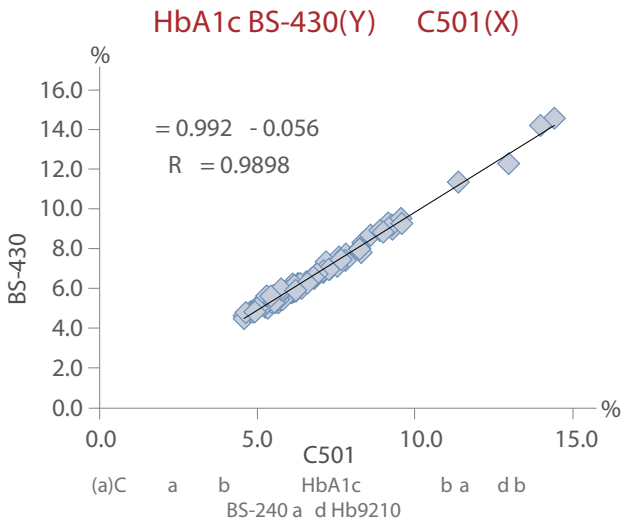
BS-240 VS Hb9210

T a Sa b	M C .	Ma C .	S	I c	R^2
120	4.5	14.6	1.006	-0.206	0.992
			Pa	/	Pa

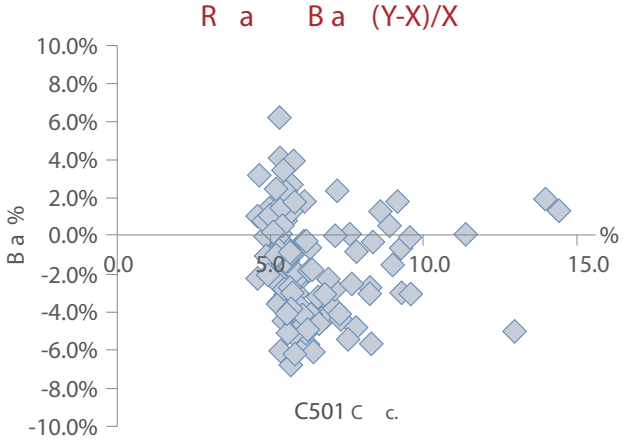
L 1 C c	6.5	L 2 C c	7	L 3 C c	8	L 4 C c	8.5	L 5 C c	9
R . Ba	Ab Ba	R . Ba	Ab Ba	R . Ba	Ab Ba	R . Ba	Ab Ba	R . Ba	Ab Ba
-2.5%	-0.2	-2.3%	-0.2	-1.9%	-0.2	-1.8%	-0.2	-1.6%	-0.1
Pa		Pa		Pa		Pa		Pa	

(c) Pa a a d a b a da a a HbA1c

F .5 M d c a b M d a BS-240 (B c a c d) a d T B c P Hb9210 (b a -a c a a d)



(a)C a b HbA1c b a d b BS-240 a d Hb9210



(b)R a B a %=(Y-X)/X Y HbA1c b a d b BS-430; X HbA1c b a d b C501.

BS-800 VS Variant II					
T a Sa b	M C .	Ma C .	S	I c	R^2
120	4.5	14.6	0.992 Pa	-0.056	0.990 Pa

L 1 C c	6.5	L 2 C c	7	L 3 C c	8	L 4 C c	8.5	L 5 C c	9
R . B a	Ab B a	R . B a	Ab B a	R . B a	Ab B a	R . B a	Ab B a	R . B a	Ab B a
-1.7%	-0.1	-1.6%	-0.1	-1.5%	-0.1	-1.5%	-0.1	-1.4%	-0.1
Pa		Pa		Pa		Pa		Pa	

(c) Pa a a d a b a da a a HbA1c

F .6 M d c a b M d a BS-430 (B c a c d) a d R c C ba C501 (a a d)

Acc d HbA1c d c a c a 2019 CLIA [3] a d 2020 CAP [4], M d a ' a c HbA1c d d d c a (R2>0.96) B -Rad Va a II HPLC (- c a c a a), T Hb9210 HPLC (b a a) a d R c C501 (b d). T a b a % a HbA1c b ac d a 5%.

ITEM	R U	2019 CLIA &2020 CAP		
		S ( )	R^2	R a B a %
HbA1c	%	1±0.05	0.95	±5.00%

Tab 1. HbA1c d c a c a

Conclusion

T ba a da d a HbA1c a a HbA1c b a d d d acc a a d c a ab .

M d a a c HbA1c c c a d d . I a b a ab a d c d a a d a HbA1c.

R c

1 H A1 : A A C A . A L M 2013; 33:393-400.

2 C A1C : A D A , E A D , I F - C C L M , I - D F . D C . 2007 ;30(9):2399-400. : 10.2337/ 07-9925.

3 2019: CLIA

4 CA (C A) 2020