HEMOGLOBIN A1C

Turbidimetry

The application parameters comprised here constitute a guide to facilitate the validation of our reagents by the instrument. It is advisable to validate the use when there is any change in software or reagent versions.

Instrument: **HITACHI 911 (= HITACHI 904)**

Samples

Capillary or venous blood collected by standard procedures and with heparin or EDTA as anticoagulants .
HbA1C in blood is stable 3 days at 15-25ºC, 7 days at 2-8ºC and 6 months at –20ºC. Freeze once only.

Hemolysate preparation

The calibrators do not require pretreatment.

1. Bring the reagent A to room temperature.
2. Pipette into a test tube:

Blood	10 µL
Reagent (A)	1000 µL

3. Shake thoroughly. Avoid the formation of foam. The hemolysate can be used after the solution has changed color from red to brownish-green (approximately 3 minutes).

The hemolysate is stable 4 hours at 15-25ºC, 24 hours at 2-8ºC and 6 months at –20ºC. Freeze once only.

Reagent preparation

Reagents (A), (B), (C) and (D) are provided ready to use.
HbA1C Standards (S1-S4): Reconstitute with 2.0 mL of distilled water. Stable for 8 hours at 15-25 ºC, 2 days at 2-8°C and 3 months at -20°C. Freeze once only.

Hb Reagent 1: Reagent B
HbA1c Reagent 1: Reagent C Reagent 2: Reagent D

Instrument settings

TOTAL HB

TEST HB	XXX	TEST NAME HB	UNIT g/dL
DATA MODE	1: ON BOARD	REPORT NAME HB	
CONTROL INTERVAL	1000	INSTRUMENT FACTOR (y=aX+b)	a 1.0 b 0.0
EXPECTED VALUE <S. TYPE 1>		EXPECTED VALUE <S. TYPE 2>	
AGE (M)	(F)		
* - *	* - *		
TECHNICAL LIMIT <S. TYPE 1>		<S. TYPE 2>	
1.10 - 40			

STD	CONC.	POS.	S.VOL.	PRE.	DIL.VOL.	CODE
(1)	0.0	L	20	0	0	99
(2)	*	...	20	0	0	...

Blank: Make reagent blank with sodium cloride 154 mmol/L.
Calibrator: Standard S4.

TEST HB		WAVELENGTH (SUB/MAIN)	660 / 570
ASSAY CODE	END POINT – 10 - 0 ASSAY POINT 15 – 0 – 0 - 0	DILUTION	301 / 99
	<S. TYPE 1>	<S. TYPE 2>	
S. VOL. (REGULAR)	20 – 0 - 0		
S. VOL. (DECREASE)	20 – 0 - 0		
S. VOL. (INCREASE)	20 – 0 - 0		
ABS. LIMIT	0	0	2: INCREASE
PROZONE LIMIT	32000		1: UPPER
REAGENT R1	230 – 0 – XXX – 28		
R2	0 – 0 – XXX - 0		
R3	0 – 0 – XXX - 0		
R4	0 – 0 – XXX - 0		
CALIB. TYPE	1: LINEAR 2 2 0		
TIME OUT BLANK	0	SD LIMIT	0.1
2 POINT	0	DUPLICATE LIMIT	100
FULL	0	SENSITIVITY LIMIT	0
CHANGE LOT	0	S1 ABS LIMIT -32000	32000
BOTTLE	0		

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HBA1C

TEST	HBA1C					XXX	TEST NAME	HBA1C	UNIT g/dL
DATA MODE						1: ON BOARD	REPORT NAME	HBA1C	
CONTROL INTERVAL						1000	INSTRUMENT FACTOR (y=aX+b)		a 1.0 b 0.0
EXPECTED VALUE	<S. TYPE 1>						EXPECTED VALUE	<S. TYPE 2>	
AGE	(M)					(F)			
	* - *					* - *			
TECHNICAL LIMIT	<S. TYPE 1>							<S. TYPE 2>	
	0.05 - 2.50								

STD	CONC.	POS.	S.VOL.	PRE.	DIL.VOL.	CODE
(1)	0.00	L	10	0	0	999
(2)	*	...	10	0	0	…
(3)	*	...	10	0	0	…
(4)	*	...	10	0	0	
(5)	*	...	10	0	0	

Blank: Make reagent blank with sodium cloride 154 mmol/L.
Calibrators 2-5: Standards S1-S4

TEST	HBA1C		WAVELENGTH (SUB/MAIN)		700 / 340
ASSAY CODE	2 POINT END – 10 - 0	ASSAY POINT 15 – 31 – 0 - 0	DILUTION		301 / 99
	<S. TYPE 1>			<S. TYPE 2>	
S. VOL. (REGULAR)	10 – 0 - 0				
S. VOL. (DECREASE)	10 – 0 - 0				
S. VOL. (INCREASE)	10 – 0 - 0				
ABS. LIMIT	0		0	2: INCREASE	
PROZONE LIMIT	0			2: LOWER	
REAGENT R1	250 – 0 – XXX – 28				
R2	0 – 0 – XXX - 0				
R3	50 – 0 – XXX - 28				
R4	0 – 0 – XXX - 0				
CALIB. TYPE	3: LOGIT-LOG (4P)	5 4 0			
TIME OUT BLANK		0	SD LIMIT		250
2 POINT		0	DUPLICATE LIMIT		400
FULL		0	SENSITIVITY LIMIT		3000
CHANGE LOT		0	S1 ABS LIMIT	-32000	32000
BOTTLE		0			

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CALCULATION

$$\%\ \text{HbA1C - IFCC} = \frac{\text{HbA1C (g/dL)}}{\text{Hb (g/dL)}} \text{ x } 100$$

The HbA_{1c} percentage in the sample is calculated using the following general formula. The values are traceable to IFCC Reference Method:

The traceable values to Reference Method as described by the US National Glycohemoglobin Standardization Program (NGSP) are calculated using the following general formula:

$$\%\text{HbA1C-NGSP} = 0.915 \text{ x } \%\text{HbA1C-IFCC} + 2.15$$