

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: CX-4-5-7

Samples

Capillary or venous blood collected by standard procedures and with heparin or EDTA as anticoagulants .
HbA1C in blood is stable 3 days at 15-25°C, 7 days at 2-8°C and 6 months at -20°C.
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 15-25°C, 24 hours at 2-8°C and 6 months at -20°C.
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 °C, 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

HB

Test Name	HB	Calculation Factor	0
Reaction Type	ENDPOINT 2	Math Model	1
Reaction Direction	POSITIVE	Cal. Time Limit	336 hr.
Units	g/dL	Nº of Calibrators	2
Decimal Precision	X.X	Secondary Wavelength	670
Primary Wavelength	560 nm	CALIBRATION	MULTIPOINT SPAN
Sample Volume	30 µL	Nº 1	0.0
Primary Inject Reagent		Nº 2	...
A:	200 µL	REACTION	
B:		Start Read	304
REAGENT BLANK		End Read	320
Start Read	250	Low ABS Limit	-1.500
End Read	300	High ABS Limit	1.500
Low ABS Limit	-1.500	SUBSTRATE DEPLETION	
High ABS Limit	1.500	Initial Rate	99.999
USABLE RANGE		Delta ABS	1.500
Lower Limit	1.10	Blank: Make reagent blank with sodium chloride 154 mmol/L	
Upper Limit	40	Calibrator: Standard S4	
... Data entered by the operator			

HBA1C

Test Name	HBA1C	Calculation Factor	0
Reaction Type	ENDPOINT 2	Math Model	1
Reaction Direction	POSITIVE	Cal. Time Limit	336 hr.
Units	g/dL	Nº of Calibrators	5
Decimal Precision	X.XX	Secondary Wavelength	700
Primary Wavelength	340 nm		
Sample Volume	8 µL	CALIBRATION	MULTIPOINT SPAN
Primary Inject Reagent		Nº 1	0.00
A:	200 µL	Nº 2	(*) S1
B:		Nº 3	(*) S2
Secondary Inject Reagent		Nº 4	(*) S3
C:	40 µL	Nº 5	(*) S4
Add Time	432 sec.	REACTION	
REAGENT BLANK		Start Read	412
Start Read	352	End Read	444
End Read	400	Low ABS Limit	-1.500
Low ABS Limit	-1.500	High ABS Limit	1.500
High ABS Limit	1.500	SUBSTRATE DEPLETION	
USABLE RANGE		Initial Rate	99.999
Lower Limit	0.05	Delta ABS	1.500
Upper Limit	2.50		
		Blank: Make reagent blank with sodium chloride 154 mmol/L. Calibrators 2-5: Standards S1-S4	

Version 0704

CALCULATION

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

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:

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