

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: AEROSET

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

OUTLINE		Dil. 2	
Test Name	Hb	S. Vol.	20
Assay #		DS. Vol.	0
Line	A	D. Vol.	0
Linear low	1.1	W. Vol.	0
Min.	1.1	Diluent	Saline
Reference low	...	Reagent 1	200
Reference high	...	W. Vol.	0
Max.	40	Reagent 2	0
Linear high	40	W. Vol.	0
BASE		Factor	1.0
Reaction mode	End up	Intercept	0.0
Primary Wavelength	548	Decimal places	1
Secondary Wavelength	660	Units	g/dL
Main read time	14-16	CALIBRATION	
Flex read time	0	Calibration mode	Linear
Abs. Max. Var.	0	Cal 1	(*) S4
Linearity %	N/A	Factor	N/A
Sample Blank Test	N/A	Use cal. Factors from	N/A
Blank read time	0	Interval	720 Hrs.
Abs. Limits	0	Blank/cal. Replicates	3/3
Sample volume (µL)	20	Blank	Water
DS. Vol.	0	S. Vol.	20
D. Vol.	0	DS. Vol.	0
W. Vol.	0	D. Vol.	0
Dil. 1		W. Vol.	0
S. Vol.	20	C1 C2	--
DS. Vol.	0	S. Vol.	0
D. Vol.	0	DS. Vol.	0
W. Vol.	0	D. Vol.	0
		W. Vol.	0
Blank: Make reagent blank with sodium chloride 154 mmol/L.			
(*) Calibrator: Standard S4			

Hb A1c

OUTLINE		Dil. 2	
Test Name	Hb A1c	S. Vol.	8
Assay #		DS. Vol.	0
Line	A	D. Vol.	0
Linear low	0.05	W. Vol.	0
Min.	0.05	Diluent	Saline
Reference low	...	Reagent 1	200
Reference high	...	W. Vol.	0
Max.	2.50	Reagent 2	40
Linear high	2.50	W. Vol.	0
		Factor	1.0
BASE		Intercept	0.0
Reaction mode	End up	Decimal places	1
Primary Wavelength	340	Units	g/dL
Secondary Wavelength	--		
Main read time	31-33	CALIBRATION	
Flex read time	14 - 16	Calibration mode	Spline
		Calibrator level	Std. 1 0.00
			Std. 2 (*) S1
			Std. 3 (*) S2
			Std. 4 (*) S3
			Std. 5 (*) S4
Abs. Max. Var.	0	Factor	N/A
Linearity %	N/A	Use cal. Factors from	N/A
Sample Blank Test	N/A	Interval	720 Hrs.
Blank read time	0	Blank/cal. Replicates	3/3
Abs. Limits	0	Blank	Water
Sample volume (µL)	8	S. Vol.	8
DS. Vol.	0	DS. Vol.	0
D. Vol.	0	D. Vol.	0
W. Vol.	0	W. Vol.	0
<u>Dil. 1</u>		C1 C2	--
S. Vol.	8	S. Vol.	0
DS. Vol.	0	DS. Vol.	0
D. Vol.	0	D. Vol.	0
W. Vol.	0	W. Vol.	0
Blank: Make reagent blank with sodium chloride 154 mmol/L.			
(*) Enter the corresponding S1-S4 standards value			

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:

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