

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: METROLAB 2300 (=DATA PIO)

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	
NAME	HB
UNITS	g/dL
WAVELENGTH	550 nm
BIC. REF.	700 nm
LOW LIMIT (men)	... g/dL
HIGH LIMIT (men)	... g/dL
LOW LIMIT (women)	... g/dL
HIGH LIMIT (women)	... g/dL
TYPE	End Point
SAMPLE VOLUME	45 µL
1 ST REAGENT VOLUME	255 µL
2 ND REAGENT VOLUME	
1 ST INCUBATION	300 sec.
2 ND INCUBATION	0 sec.
LINEAR LIMIT	40 g/dL
CONSUMPTION LIMIT (KINETICS)	
REFERENCE	Standard
FACTOR/STANDARD	Standard *
REACTION DIRECTION	Increasing
	Blank: Make reagent blank with sodium chloride 154 mmol/L.
	(*) Calibrator: Standard S4

	(...)Values entered by the operator
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Version 0611

HbA1c

NAME	HB A1c	
UNITS	g/dL	
WAVELENGTH	340 nm	
BIC. REF.		
LOW LIMIT (men)	... g/dL	
HIGH LIMIT (men)	... g/dL	
LOW LIMIT (women)	... g/dL	
HIGH LIMIT (women)	... g/dL	
TYPE	End Point	
SAMPLE VOLUME	12 µL	
1ST REAGENT VOLUME	300 µL	
2ND REAGENT VOLUME	60 µL	
1ST INCUBATION	300 sec.	
2ND INCUBATION	660 sec.	
LINEAR LIMIT	2'50 g/dL	
CONSUMPTION LIMIT (KINETICS)		
REFERENCE	Standard	
FACTOR/STANDARD	Blank	Water (conc: 0)
	Cal 1	S1*
	Cal 2	S2*
	Cal 3	S3*
	Cal 4	S4*
REACTION DIRECTION	Increasing	
(...)Values entered by the operator	Blank: Make reagent blank with sodium chloride 154 mmol/L. (*) Calibrators 2-5: Standards S1-S4	

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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:

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