

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: **AU 400 / 640**

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

Specific Test Parameters					
Sample: Volume	20 µL	Dilution	0 µL	Reagent OD limit:	
Reagents: R1 Volume	140 µL	Dilution	0 µL	First L	-2.0 First H 2.5
R2 Volume	µL			Last L	-2.0 Last H 2.5
Wavelength: Pri.	540	Sec.	660	Dynamic Range:	
Method:	END			L	0 H #
Reaction slope:	+			Correlation Factor:	A 1 B 0
Measuring Point 1: First	0	Last	16	On-board stability period:	
Measuring Point 2: First		Last		L	H
Linearity:	%			#	#
No Lag Time:				L	H
7. None selected					
8. Out of range					
Panic Value		L	H	Unit: g/dL	Decimal places: 1
Calibration Specific					
Calibration Type:	AB	Formula:	Y = AX + B	Counts:	2 Process: CONC.
	Cal. N°	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		0.0	-2.0	2.5
Point 2:	#		*	-2.0	2.5
Blank: Make reagent blank with sodium chloride 154 mmol/L.					
Calibrator: Standard S4					

HbA1C

Specific Test Parameters					
Sample:	Volume	5 µL	Dilution	0 µL	
Reagents:	R1 Volume	125 µL	Dilution	0 µL	Reagent OD limit:
	R2 Volume	25 µL			First L -2.0 First H 2.5
Wavelength:	Pri.	340	Sec.	700	Last L -2.0 Last H 2.5
Method:	FIXED				
Reaction slope:	+				
Measuring Point 1:	First	16	Last	27	Dynamic Range:
Measuring Point 2:	First		Last		L 0 H #
Linearity:	%				
No Lag Time:					
					Correlation Factor:
					A 1 B 0
					On-board stability period:
					L H
7. None selected					
8. Out of range					# #
					L H
Panic Value					Unit: g/dL Decimal places: 2
Calibration Specific					
Calibration Type:	5AB		Formula:	POLYGONAL	
	Counts:	2		Process:	CONC.
	Cal. N°	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		0.00	-2.0	2.5
Point 2:	#		*	-2.0	2.5
Point 3:	#		*	-2.0	2.5
Point 4:	#		*	-2.0	2.5
Point 5:	#		*	-2.0	2.5
Blank: Make reagent blank with sodium chloride 154 mmol/L.					
# User defined					
Calibrators 2-5: Standards S1-S4					

Version 0508

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:

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