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: **ALCYON 300 (=FALCOR)**

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

HB

Type	End Pt.	Primary Wavelength	550
Unit	g/dL	High Wavelength	---
Number of decimals	1	Low Wavelength	---
Diluent	99 Diluent	Systematic serum blank	NO
Pre-washing	NO	T Tolerance Factor	0.010
First reagent vol. (µl)	200	Antigen Excess test (%)	NO
Second reagent vol. (µl)			
Sample Volume (µl)	20.0	Slope	1.00
		Intercept	0.00
Lower normal value	...		
Higher normal value	...	Reaction delay	05:00
Dilution factor	1	Incubation	00:00
Systematic dilution	1	Total	05:00
Dilution For Urine	1		
Low Reagent Blank	0.0000		
High Reagent Blank	3.5000		
Maximum Deviation	0.0500		
(...) Data entered by the operator		Blank: Make reagent blank with sodium cloride 154 mmol/L. Calibrators S4	

HBA1C

Type	Kin. 1	Primary Wavelength	340
Unit	g/dL	High Wavelength	---
Number of decimals	1	Low Wavelength	---
Diluent	99 Diluent	Systematic serum blank	NO
Pre-washing	NO	T Tolerance Factor	0.010
First reagent vol. (µl)	250	Antigen Excess test (%)	0.005
Second reagent vol. (µl)	50	Slope	1.00
Sample Volume (µl)	10.0	Intercept	0.00
Lower normal value		2nd Reagent dispense delay	05:00
Higher normal value		Reaction delay	05:00
Dilution factor	1	Incubation	00:00
Systematic dilution	1	Total	05:00
Dilution For Urine	1	Calibration Curve	Simple Model
Low Reagent Blank	0.0000	Polynomial Degree	3
High Reagent Blank	3.5000	Correlation Limit	0.80
Maximum Deviation	0.0500	Main Calibrator	2
... Data entered by the operator		Blank: Make reagent blank with sodium cloride 154 mmol/L. Calibrators 2-5: Standards S1-S4	

Vers. 0604

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:

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