

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: **MEGA**

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								
PHOTOMETRIC Report								
Normal Range L/H		... / ...		Slope(%) / Intercept A		100 / 0		
Meas. Range L/H		1.1 / 40		Slope(%) / Intercept B		100 / 0		
Decimal point loc.		1		Unit		g/dL		
Absorbance Window		0 / 0						
Calibrators								
Factor	Calibrator Name	Conc.	Abs/Act.	Factor	S.V.	Dil-Sample	Limits	L/H
C 0	...	*	0		40.0	0.0	0.0 / ...	0
C 1	Calibra 1	(*) S4			40.0	0.0	0.0 / ...	0
PHOTOMETRIC TEST								
Assay				Sample				
Measuring mode		End		Determin. Per sample		1		
Up/Down		Up		Sample Vol./Dil. Vol.		40.0 / 0.0		
Sample blank Test				Rerun/Dil. Vol.		2.0 / 0.0		
Main/Sub W.L. (nm)		550 / 660		Reagent		ID	Vol.	H2O
Calibration refer				Reagent 1		...	225	0
Test read interval		60 – 68		Reagent 2				
Blank read interval		0 – 0		Diluent				
Absorbance window		-0.100 / 2.5		Rerun Diluent				
Calibration				Reaction check				
Blank/Cal. – determin.		2 / 2		Endpoint check (Abs.)		0.000		
Type		Linear		Multiple determ. Range		0		
				Mono/Bi-chromatic		Main		
				Ratio/Differ check		Differ		
				End/Rate		End		
				Test read interval 1		0 – 0		
				Test read interval 2		0 – 0		
				Check limits L/H		0 / 0		
... Data entered by the operator Blank: Make reagent blank with sodium chloride 154 mmol/L. Calibrator: Standard S4.								

HbA1c

PHOTOMETRIC Report								
Normal Range L/H	... / ...			Slope(%) / Intercept A	100 / 0			
Meas. Range L/H	0.05 / 2.50			Slope(%) / Intercept B	100 / 0			
Decimal point loc.	1			Unit	g/dL			
Absorbance Window	0 / 0							
Calibrators								
Factor	Calibrator Name	Conc.	Abs/Act.	Factor	S.V.	Dil-Sample	Limits	L/H
	C 0 ...	0.00	0		8.0	0.0	0.0 / ...	0
	C 1 Calibra 1	(*) S1			8.0	0.0	0.0 / ...	0
	C 2 Calibra 2	(*) S2			8.0	0.0	0.0 / ...	0
	C 3 Calibra 3	(*) S3			8.0	0.0	0.0 / ...	0
	C 4 Calibra 4	(*) S4			8.0	0.0	0.0 / ...	0
PHOTOMETRIC TEST								
Assay				Sample				
Measuring mode	Two points			Determin. Per sample	1			
Up/Down	Up			Sample Vol./Dil. Vol.	8.0 / 0.0			
Sample blank Test				Rerun/Dil. Vol.	2.0 / 0.0			
Main/Sub W.L. (nm)	340 / ---			Reagent	ID	Vol.	H2O	
Calibration refer				Reagent 1	...	200	0	
Test read interval	126 - 134			Reagent 2	40			
Blank read interval	61 - 69			Diluent				
Absorbance window	-0.100 / 2.5			Rerun Diluent				
Calibration				Reaction check				
Blank/Cal. - determin.	2 / 2			Endpoint check (Abs.)	0.000			
Type	Curve			Multiple determ. Range	0			
				Mono/Bi-chromatic	Main			
				Ratio/Differ check	Differ			
				End/Rate	End			
				Test read interval 1	0 - 0			
				Test read interval 2	0 - 0			
				Check limits L/H	0 / 0			
... Data entered by the operator								
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:

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