

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: ARCHITECT C8000

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

GENERAL				CALIBRATION			
Reaction definition				Calibrators			
Assay				Calibration method			
Type				Calibrator set			
Reaction mode				Calibrator level			
Wavelength				Blank			
Read times				Cal 1			
Last required read				Volumes			
Absorbance				Calibrator			
Sample blank type				Cali. level			
Blank				Sample			
Reagent/Sample				Dil. Sample			
Reagent				Diluent			
Reagent volume				Water			
Diluent				Blank Water			
Water volume				Cal 1 Hb			
Diluent dispense mode				Intervals			
Dispense mode				Full intervals			
Dilution name				Adjust type			
Default				Validity checks			
Validity check				Blank absorbance range			
Reaction check				Span			
Rate linearity %				Span absorbance range			
Blank: Make reagent blank with sodium chloride 154 mmol/L.				Expected cal factor			
(*) Calibrator: Standard S4				Expected cal factor tolerance %			
				Results			
				Low Linearity			
				High Linearity			

HbA1c

GENERAL				CALIBRATION			
Reaction definition				Calibrators			
Assay		HbA1c		Calibration method		Spline	
Type		Photometric		Calibrator set		S	
Reaction mode		End up		Calibrator level		Blank Water (conc: 0)	
Wavelength		Primary	340	Cal 1	S4 *		
		Secondary	None	Cal 2	S3*		
				Cal 3	S2*		
				Cal 4	S1*		
Read times		Main	31 – 33	<i>Volumes</i>			
		Flex		Calibrator			
Last required read		33		Cali. level		Sample	Dil. Sample
Absorbance				Blank Water		8.0	Diluent
Sample blank type		Self		Cal 1 HbA1c		8.0	Water
<i>Blank</i>		14 - 16		<i>Intervals</i>			
Reagent/Sample				Full intervals		999 hours	
Reagent		HbA1c		<i>Adjust type</i>		none	
Reagent volume		R1	200	<i>Validity checks</i>			
Diluent				Blank absorbance range		0.0000 – 0.0000	
Water volume				Span		Blank – Blank	
Reagent volume		R2	40	Span absorbance range		0.0000 – 0.0000	
Diluent				Expected cal factor		0.0000	
Water volume				Expected cal factor tolerance %		0	
Diluent dispense mode		Type 0		<i>Results</i>			
Dispense mode		R1	Type 0	Low Linearity		0.05	
		R2	Type 0	High Linearity		2.50	
Dilution name		Sample	Water				
Default		8		Dilution factor			
				1:1.00			
<i>Validity check</i>							
Reaction check		None					
Rate linearity %							
Blank: Make reagent blank with sodium chloride 154 mmol/L.							
(*) Calibrators 2-5: Standards S1-S4							

Vers. 0611

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:

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