

# 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.

## Instruments: DIMENSION AR / RxL

### 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**

Test:	<b>Hb</b>		Name:	<b>Hb</b>		
Channel:	<b>(***)</b>		Method:	<b>Normal</b>		Std. Curve: <b>Linear</b>
Measure:	<b>End Point</b>		Ref. Wavelength:	<b>700 nm</b>		
Act. Wavelength:	<b>577 nm</b>					
Sample			Dilution	<b>Mix moderate</b>		
Time	Volume					
<b>0.0</b>	<b>30 µL</b>		<b>0 µL</b>			
Reagent delivery time			Dilution	<b>Mix moderate</b>		
Time	Comp.1	Comp.2/3				
1.: <b>-57.6</b>	<b>(A) 170 µL</b>		<b>0 µL</b>			
2.:						
3.:						
Photometry			1	2	3	4
Time	Factor		5	6		
1.: <b>332 sec</b>	<b>- 1.000</b>		Comp	<b>(A)</b>	<b>(A)</b>	<b>(A)</b>
2.:			Aliquote	14	14	14
				14	14	70
Method parameter			Decimal places:	<b>1</b>		
Method:	<b>Hb</b>		Calculation:	<b>Linear</b>		
Units:	<b>g/dL</b>		Std. 1	<b>0.0</b>		
			Std. 2	<b>(*) S4</b>		
Serum/Plasma	Normal Range	Technical Range				
	<b>... - ...</b>	<b>1.1 - 40</b>				
(...) Data entry by the user			Blank: Make reagent blank with sodium chloride 154 mmol/L. (*) Calibrator: Standard S4.			

**HbA1C**

Test: <b>Hb A1c</b>		Name: <b>Hb A1c</b>		Std. Curve: <b>Logit</b>	
Channel: <b>(***)</b>		Method: <b>Normal</b>			
Measure: <b>End Point</b>		Ref. Wavelength:			
Act. Wavelength: <b>340 nm</b>					
Sample					
Time	Volume	Dilution	Mix		
<b>0.0</b>	<b>12 µL</b>	<b>0 µL</b>	<b>moderate</b>		
Reagent delivery time					
Time	Comp.1	Comp.2/3	Dilution	Mix	
1.: <b>-60.0</b>	<b>(A) 300 µL</b>		<b>0 µL</b>	<b>moderate</b>	
2.: <b>257.3</b>	<b>(B) 60 µL</b>		<b>0 µL</b>	<b>moderate</b>	
3.:					
Photometry					
Time	Factor		1	2	3
1.: <b>230 sec</b>	<b>- 1.000</b>		<b>(A)</b>	<b>(A)</b>	<b>(A)</b>
2.: <b>557 sec</b>	<b>1.000</b>		Comp	4	5
			Aliquote	14	14
				6	70
				(A)	(B)
Method parameter					
Method:	<b>Hb A1c</b>	Decimal places:	<b>1</b>		
Units:	<b>g/dL</b>	Calculation:	<b>Logit</b>		
		Std. 1	<b>0.0</b>		
		Std. 2	<b>(*) S4</b>		
		Std. 3	<b>(*) S3</b>		
		Std. 4	<b>(*) S2</b>		
		Std. 5	<b>(*) S1</b>		
	<b>Normal Range</b>	<b>Technical Range</b>			
Serum/Plasma	<b>... - ...</b>	<b>0.05 – 2.50</b>			
Blank: Make reagent blank with sodium chloride 154 mmol/L.					
(***) Data entry by the user					
(*) 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<sub>1c</sub> 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:

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