

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: **RX-DAYTONA (=BQA, CHEMIX-180)**

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

CHEMISTRY PARAMETERS				HB	R1	Reagent Name	HB	Volume 200 µL	
Name			g/dL		R2	Reagent Name			
Unit			End						
Assay Type									
Measuring Points	1	Start			Decimal points	1			
		End			Normal Range (Male)		
	2	Start	13		(Female)		
		End	13		(Child)		
Wavelength					Technical Range (Conc.)	1.1	-	40	
Prim.	600		Sec.		(mAbs/10)	-25000	-	25000	
Sampling Volume	20 µL				RPT Wash (R1)	Sys Water		Wash Sol.-3	
Rerun	2 µL				(R2)	Sys Water		Wash Sol.-3	
CALIBRATION				S1	0.0				
Calculation	Linear		S2	...	Instrument Factor	a	1	b	0
					Stirring Speed	R1	Mid	R2	Mid
Blank: Make reagent blank with sodium chloride 154 mmol/L. Calibrator: Standard S4				... Data entered by the operator					

HBA1C

CHEMISTRY PARAMETERS													
Name				HBA1C	R1	Reagent Name	HBA1C	Volume	200 µL				
Unit				g/dL	R2	Reagent Name	HBA1C	Volume	40 µL				
Assay Type	End												
Measuring Points	1	Start	13			Decimal points	2						
		End	13										
Measuring Points	2	Start	26			Normal Range							
		End	26							(Male)	...	-	...
										(Female)	...	-	...
(Child)	...	-	...										
Wavelength	Prim.	340	Sec.			Technical Range	(Conc.)	0.05	-	2.5			
											(mAbs/10)	-25000	-
Sampling Volume		8 µL				RPT Wash (R1)	Sys Water		Wash Sol.-3				
Rerun		2 µL				(R2)	Sys Water		Wash Sol.-3				
CALIBRATION				S1	0.0	Instrument Factor							
Calculation	Log-Logit			S2	(*) S1	Stirring Speed							
				S3	(*) S2	a	1	b	0				
				S4	(*) S3	R1	Mid	R2	Mid				
				S5	(*) S4								
							... Data entered by the operator						
Blank: Make reagent blank with sodium chloride 154 mmol/L.													
Calibrators 2-5: Standards S1-S4													

Version 0705

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:

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