

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: **BT TARGA 2000/3000 (=ATAC 8000)**

Hemolysate preparation

The calibrators do not require pretreatment.

1. Bring the reagent A to room temperature.
2. Pipette into a test tube:

Blood	10 μ L
Reagent (A)	1000 μ L

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 Type	End Point Single
Serum Starter	Inactive
Filters (A/B)	546 700
Units	g/dL
Test Method	Linear
Test Methodology	
Number of Washes	1
Delay Time (Sec)	0
Inc. Reagent (Sec)	300
Reading Time (Sec)	20
Test Limit (Conc)	40
Max Abs Delta (mABS)	300
Reagent mABS Limit	1400
Reagent A/B (μ L)	300
Reaction Direction	Increasing
Reagent Dilution	1:1
Initial ABS (mABS)	1999
Curve Acceptance	100 %
Automatic Profile (Inactive)	
Rerun Test Rgt BLK H:M	00:00
<i>Serum Parameters</i>	
Test's Name	Hemoglobin
Sample Volume (μ L)	30
Dilution Ratio	1:2
Min. Max. M	... - ...
Min. Max. F	... - ...
Min. Max. B	... - ...
.. Data entered by the operator	
Blank: Make reagent blank with sodium chloride 154 mmol/L.	
(*) Input the assigned value of the calibrator Calibrator: Standard S4	

HbA1c

Test Type		End point with Starter
Serum Starter		Inactive
Filters	(A/B)	340
Units		g/dL
Test Method		Cubic Spline
Test Methodology		
Number of Washes		1 1
Delay Time	(Sec)	420
Inc. Reagent	(Sec)	0 120
Reading Time	(Sec)	10
Test Limit	(Conc)	2.5
Max Abs Delta	(mABS)	300
Reagent mABS Limit		1400
Reagent A/B	(μ L)	250 50
Reaction Direction		Increasing
Reagent Dilution		1:1
Initial ABS	(mABS)	1999
Curve Acceptance		100 %
Automatic Profile	(Inactive)	
Rerun Test Rgt BLK H:M		00:00
<i>Serum Parameters</i>		
Test's Name		HbA1c
Sample Volume	(μ L)	10
Dilution Ratio		1:2
Min. Max. M		... - ...
Min. Max. F		... - ...
Calibrators 2-5: Standards S1-S4		Blank: Make reagent blank with sodium chloride 154 mmol/L.
... Data entered by the operator		

Vers. 0609

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:

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