

# 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: **ILAB 600 (=SHIMADZU CL-8000 / TBA-60FR)**

### 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. F

### 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 NAME	Hb
SAMPLE TYPE	Whole blood
UNITS. DECIMAL POINTS	g/dL 0
CYCLE	Standard
TYPE/MEASURE POINTS	End point 28
PHOTO.PRIM/SEC	2 570 660
WAVELENGTHS	
<i>SAMPLE VOLUME AND DILUTION</i>	
1 <sup>ST</sup> SAMPLE SAMPLE/DILUENT	30 / 0 / 0
2 <sup>ND</sup> SAMPLE SAMPLE/DILUENT	0 / 0 / 0
DILUENT CODE	Water
<i>REAGENT VOLUME</i>	
R1 CODE	*
REAGENT VOL/DIL. VOL/MIX	170 10 *
STABILITY	28 days
R2 CODE	
REAGENT VOL/DIL. VOL/MIX	
STABILITY	
<i>LIMITS AND EVALUATION</i>	
MEASURING RANGE	1.3/ 40
REACTION	Positive
ABSORBTION LIMIT	Upper 3500
SLOPE - OFF LIMITS	1.0 0.0
PROZONE JUDGE, LIMIT	Upper 100
<i>CALIBRATION</i>	
METHOD	1-Point
WDH/CUVE/STABILITY	3 Linear 28
CALIBRATOR/CONC	S4 (*)
R-BLANK LIMIT	3500
ABW-CALIBRATOR	100
MIN SIGNAL	0
FACTOR	100
M-POINT CUVE FIT	50
R-BLANK	On

\* Values Assigned by the operator

## Instrument settings

### Hb A1c

TEST NAME	Hb A1c
SAMPLE TYPE	Whole blood
UNITS. DECIMAL POINTS	g/dL 0
CYCLE	Standard
TYPE/MEASURE POINTS	Two end point 16 28
PHOTO.PRIM/SEC	1 340
WAVELENGTHS	
<i>SAMPLE VOLUME AND DILUTION</i>	
1 <sup>ST</sup> SAMPLE SAMPLE/DILUENT	8 / 0 / 0
2 <sup>ND</sup> SAMPLE SAMPLE/DILUENT	0 / 0 / 0
DILUENT CODE	Water
<i>REAGENT VOLUME</i>	
R1 CODE	*
REAGENT VOL/DIL. VOL/MIX	200 0 *
STABILITY	28 days
R2 CODE	*
REAGENT VOL/DIL. VOL/MIX	40 0 *
STABILITY	28 days
<i>LIMITS AND EVALUATION</i>	
MEASURING RANGE	0.07 / 2.5
REACTION	Positive
ABSORPTION LIMIT	Upper 3500
SLOPE - OFF LIMITS	1.0 0.0
PROZONE JUDGE, LIMIT	Upper 100
<i>CALIBRATION</i>	
METHOD	Curve
WDH/CUVE/STABILITY	4 log logit
CALIBRATOR/CONC	S (0)
	S4 (*)
	S3 (*)
	S2 (*)
	S1 (*)
R-BLANK LIMIT	3500
ABW-CALIBRATOR	100
MIN SIGNAL	0
FACTOR	100
M-POINT CUVE FIT	50
R-BLANK	On
	* Values Assigned by the operator

Vers.0802

### CALCULATION

The HbA<sub>1c</sub> percentage in the sample is calculated using the following general formula:

$$\% \text{ HbA1C - IFCC} = \frac{\text{HbA1C (g/dL)}}{\text{Hb (g/dL)}} \times 100$$

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:

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