

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 300 / 300 Plus (=LIASYS)**

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

		Reference Range												
		NORMAL VALUES				HIGH VALUES								
Description	Hb													
Unit	g/dL	0.00	0.00	0.00	0.00	18.00	20.00	20.00						
Decimals	2	0.00	0.00	0.00	0.00	18.00	20.00	20.00						
LIS Code	...	0.00	0.00	0.00	0.00	18.00	20.00	54.00						
Unit Factor	1.00	Low Alert			Normal Values		High	High Alert						
Slope	1.00	Very Low	Low					Very High						
Intercept	0.00	No	No					No						
		Parameters												
Reaction Type	End Point	Predilut.	S+R 1	Reag 2	Reag 3	Incub.	Read							
Direction	Up		0	0	0	296	0							
E.P.Limit (Abs)	1.0000		Hb	0										
Depl.limit (Abs)	N/A													
First Limit (Abs)	N/A	1/1	170	0	0									
Linear Factor	N/A		0	0	0									
Fit:	N/A		30											
Lin Limit Low	0.00	RBL min (abs)		0.0										
Lin Limit High	20	Max (abs)		1.0										
Rerun when over	No	<table border="1"> <tr> <td>Filter 1 (nm) :</td> <td>546</td> </tr> <tr> <td>Filter 2 (nm) :</td> <td>none</td> </tr> <tr> <td>Bicr.Factor :</td> <td>1.00</td> </tr> </table>							Filter 1 (nm) :	546	Filter 2 (nm) :	none	Bicr.Factor :	1.00
Filter 1 (nm) :	546													
Filter 2 (nm) :	none													
Bicr.Factor :	1.00													
Calculation Model	Standard	RBL stability (days) :		1										
Factor	N/A	Calibration Stability (days):		99										
Sample Blank	No	Dynamic Controls (min):		none										
(..) Value entered by the operator		Blank: Make reagent blank with sodium chloride 154 mmol/L Calibrator: Standard S4												

