

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: **CLINLINE 150 (=LISA, MASCOTT Plus)**

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



TEST NAME	HB	BLANK = STD	YES
SHORT NAME	HB	N° OF STD	2
UNITS	g/dL	STANDARD 1 VALUE	*
ASSAY TYPE	E.P. STD	STANDARD 1 POSITION	...
FILTER VALUE	540	STANDARD 2 VALUE	*
1 ST READING = 0	NO	STANDARD 2 POSITION	...
LAG PHASE 1	0	N° REP. STANDARD/CONTROL	1
N° OF MEASURES	12	CONTROL VALUE	*
REAGENT 1 VOLUME	250	CONTROL POSITION	...
REAGENT 1 DILUTION	0	CONTROL DEVIATION	*
REAGENT 1 POSITION	...	PREDILUTION RATE	1
REAGENT 2 VOLUME	0	POSTDILUTION RATE	5
REAGENT 2 DILUTION	0	DILUENT	WATER
REAGENT 2 POSITION	...	RINSE TYPE	3
SAMPLE VOLUME	20	UP. NORMAL VALUE	*
SAMPLE DILUENT		LOW NORMAL VALUE	*
ACTIVATION	ANY	LINEARITY LIMIT	40
LAG PHASE 2T		LOWER BLANK LIMIT	1.1
FACTOR		UPPER BLANK LIMIT	1500
STD CALCULATION	1 DEG		
Blank: Make reagent blank with sodium chloride 154 mmol/L Calibrator: Standard S4			

HBA1C

TEST NAME	HBA1C	BLANK = STD	YES
SHORT NAME	HBA1C	N° OF STD	5
UNITS	g/dL	STANDARD 1 VALUE	*
ASSAY TYPE	E.P. STD	STANDARD 1 POSITION	...
FILTER VALUE	340	STANDARD 2 VALUE	*
1 ST READING = 0	NO	STANDARD 2 POSITION	...
LAG PHASE 1	10	STANDARD 3 VALUE	*
N° OF MEASURES	15	STANDARD 3 POSITION	...
REAGENT 1 VOLUME	240	STANDARD 4 VALUE	*
REAGENT 1 DILUTION	0	STANDARD 4 POSITION	...
REAGENT 1 POSITION	...	STANDARD 5 VALUE	*
REAGENT 2 VOLUME	60	STANDARD 5 POSITION	...
REAGENT 2 DILUTION	0	N° REP. STANDARD/CONTROL	1
REAGENT 2 POSITION	...	CONTROL VALUE	*
SAMPLE VOLUME	10	CONTROL POSITION	...
SAMPLE DILUENT		CONTROL DEVIATION	*
ACTIVATION	REAGENT 2	PREDILUTION RATE	1
LAG PHASE 2T		POSTDILUTION RATE	5
FACTOR		DILUENT	WATER
STD CALCULATION	4 DEG	RINSE TYPE	3
		UP. NORMAL VALUE	*
		LOW NORMAL VALUE	*
STD 1: Sodium Chloride 154 mmol/L (NaCl 0.9%)		LINEARITY LIMIT	2.5
STD 2: S1 STD 3: S2 STD 4: S3 STD 5: S4		LOWER BLANK LIMIT	0.05
		UPPER BLANK LIMIT	1500

Version 0704

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:

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