

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.

Instruments: **RA-XT (=OPERA)**

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

CHEM. #	(*)
NAME	Hb
IMMUNOASSAY	NO
TYPE	ENDPOINT
INVERSE	NO
% SAMPLE VOL.	60 (30 µL)
FILTER P.	5 (WL 550)
BIC. CHEMISTRY	NO
DELAY TIME	5 SP 00
% REAGENT VOL.	(µL)
2 ND REAGENT	NO
% 2 ND REAGENT	60 (300 µL)
A2 DELAY	0 SP 00
UNITS	g/dL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.800
RANGE LOW	1.1
RANGE HIGH	40
CAL. FACTOR (**)	1
Std.1	(*) S4
NORMAL LOW	2
NORMAL HIGH	10
SLOPE	1
INTERCEPTION	0
ENDPOINT LIMIT	0.010
Blank: Make reagent blank with sodium chloride 154 mmol/L (NaCl 0.9%).	(**) CAL. FACTOR is determined by a calibration assay.
(*) Data entered by the operator	(*) Assigned value of the Standard S4.

Hb A1c

CHEM. #	(*)
NAME	Hb A1c
IMMUNOASSAY	YES
TYPE	ZERO ORDER
INVERSE	NO
% SAMPLE VOL.	24 (12 µL)
FILTER P.	1 (WL 340)
BIC. CHEMISTRY	NO
DELAY TIME	5 SP 00
% REAGENT VOL.	60 (300 µL)
2 ND REAGENT	YES
% 2 ND REAGENT	12 (60 µL)
A2 DELAY	5 SP 00
UNITS	g/dL
UNIT FACTOR	1.000
DECIMAL	0
RBL. LOW	0.000
RBL. HIGH	0.800
RANGE LOW	0.05
RANGE HIGH	2.50
NORMAL LOW	0.00
NORMAL HIGH	10.00
SLOPE	1.00
INTERCEPTION	0.00
ENDPOINT LIMIT	0.150
IA TYPE	SIMPLE CUBIC
N° OF STANDARDS	4
N° OF ASPIRATIONS	1
STANDARD 1-4	***
%PRECISION /DEVIATION LIMIT 1	99
%PRECISION /DEVIATION LIMIT 2	15
%PRECISION /DEVIATION LIMIT 3	10
%PRECISION /DEVIATION LIMIT 4	10
R EXP (10) (50) (90)	0.0
% A DEV (10) (50) (90)	99
RSS LIMIT	9999.9
Blank: Make reagent blank with sodium chloride 154 mmol/L (NaCl 0.9%).	(**) CAL. FACTOR is determined by a calibration assay
(*) Data entered by the operator	(...) Calibrator expected values S1- S4

Version 0702

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:

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