

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: **KONELAB 20/30/60**

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 definition	Hb Total			TEST FLOW	
Test type	Photometric			Blank	Yes
Full name	Hb Total			Antigen excess	No
Online name	Hb Total			Reagent name	Hb Total
Result unit	g/dL			Reagent volume (μ L)	170
Number of decimals	1			Disp. With	Water
Acceptance	Automatic			Diluent volume (μ L)	10
Dilution 1+	0			Wash reagent	None
Sample type	Whole Blood			Sample volume (μ L)	30.0
Test in use	Yes			Disp. With	Water
Test limit (low/high)	1.1 / 40			Diluent volume (μ L)	10
Initial absorbance (min/max)	0 / 1.0			Extra wash	No
Dilution limit (low/high)	3 / 120			Incubation time (sec)	300
Secondary dil. 1+	2			Measurement	End point, blank
Reference class	Low	High	In use	Reagent name	-
M.	yes	Reagent volume (μ L)	-
F.	yes	Disp. With	-
Correction factor	1			Diluent volume (μ L)	-
Correction bias	0			Wash reagent	-
CALIBRATION PARAMETERS				Incubation time (sec)	-
Calibration type	Linear			Measurement	End Point
Point/std	1			Wavelength (nm)	600
Acceptance	Automatic			Side wavelength (nm)	700
Type of standards	Separate			Meas. Type	Normal
Calibrator	Conc.			Dil. Ratio	1 + 0
	Std. 1	*		Abs. Error (mA)	5.0
... Data entered by the operator				Rel. Error (%)	2.0
Calibrators: Standards S4				Bias correction in use	no
Blank: Make reagent blank with sodium chloride 154 mmol/L.					

Hb A1c

Test definition Test type Full name Online name Result unit Number of decimals Acceptance Dilution 1+ Sample type Test in use Test limit (low/high) Initial absorbance (min/max) Dilution limit (low/high) Secondary dil. 1+ Reference class M. F. Correction factor Correction bias	Hb A1c Photometric Hb A1c Hb A1c g/dL 0 Automatic 0 Whole Blood Yes 0.05 / 2.50 0 / 1.0 * / 7.50 2 Low High In use yes yes 1 0	TEST FLOW Blank Antigen excess Reagent name Reagent volume (µL) Disp. With Diluent volume (µL) Wash reagent Sample volume (µL) Disp. With Diluent volume (µL) Extra wash Incubation time (sec) Measurement Reagent name Reagent volume (µL) Disp. With Diluent volume (µL) Wash reagent Incubation time (sec) Measurement Wavelength (nm) Side wavelength (nm) Meas. Type	Yes No Hb A1c 1 150 Water 10 None 6.0 Water 10 No 300 End point, blank Hb A1c 2 30 Water 10 None 300 End point 340 None Normal
CALIBRATION PARAMETERS Calibration type Point/std Acceptance Type of standards Calibrator	Nonlinear 4 Automatic Separate Conc. 0.00 (*) S1 (*) S2 (*) S3 (*) S4	Dil. Ratio Abs. Error (mA) Rel. Error (%) Bias correction in use	1 + 0 5.0 2.0 no
... Data entered by the operator Calibrators 2-5: Standards S1-S4 Blank: Make reagent blank with sodium chloride 154 mmol/L.			

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:

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