

# 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: EXPRESS 550 / 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

**Hb**

Test Name	Hb	Test	Hb
Test Bar Code		Curve Type	Blanked Linear
Test Type	End Point	Nr. of Decimal Places	1
Units	g/dL	Secondary Wavelength	No
Primary Wavelength	570	Sample Blank	No
Read Time/Interval	20	Nr. of Replicates	2
Factor	1	High Blank A Limit	2.500
Calibration Interval	168 hours	High A Limit	2.000
Nr. of Calibrators	2	High Normal	...
Low Blank A Limit	-0.100	Curve S.D. Limit	15.0
Low A Limit	-0.100	Test	HB
Low Normal	0	Predilution Ratio	1
Linearity Limit	40		
Sample Volume	25 µL		
Rerun Dilution Ratio	1		
Sample Diluent Bottle Type	*		
Reagent Diluent Bottle Type	*		
Reagent 1	Reagent Volume 250 µL	Bar Code Hb	Diluent Volume Lag Time 280 sec.
Reagent 2			Bottle Type *
... Data entered by the operator		Calibrator: Standard S4 Blank: Make reagent blank with sodium chloride 154 mmol/L.	

**HbA1C**

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Vers. 0703

**CALCULATION**

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

The HbA<sub>1c</sub> 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:

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