

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: **SELECTRA-2/E (=FLEXOR)**

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		
Name	HB	Max. inaccuracy	1.000 %	
Mode	Endpoint	Prozone Check	No	
Wavelength	546 nm	Ref. Male Low		
Units	g/dL	Ref. Male High		
Decimals	1	Ref. Female Low		
Low Concentration	1.1 g/dL	Ref. Female High		
High Concentration	40 g/dL	Correlation Factor	1.000	
Calibrator Name	(...)	Correlation Offset	0.000	
Repeat	2			
Number	1			
Concentration	(*) S4			
Interval	(...)			
Cut-off	No			
DUAL MODE				
Name	HB	Low Absorbance	-0.100	
Sample Blank	No	High Absorbance	3.000	
R1 Bottle	25 mL	R. Abs. Low Limit	-0.100	
Normal Volume	220 µL	R. Abs. High Limit	0.300	
Rerun Volume	220 µL	Substrate Depletion	3.000	
Sample		Reagent Blank	Yes	
Normal Volume	30 µL	Cal. Low Limit	(...)	
Rerun Volume	10 µL	Cal. High Limit	(...)	
Predilution	No	Factor		
Slope Blank	No			
Point one, two	4.5 min.			
... Data entered by the operator		Blank: Make reagent blank with sodium chloride 154 mmol/L		
(*) Enter the assigned value of standard S4				

HbA1C

Name	HbA1C	Max. inaccuracy	1.000 %
Mode	Endpoint	Prozone Check	No
Wavelength	340 nm	Ref. Male Low	
Units	g/dL	Ref. Male High	
Decimals	2	Ref. Female Low	
Low Concentration	0.05 g/dL	Ref. Female High	
High Concentration	2.50 g/dL		
Calibrator Name	(*) S1-S4	Correlation Factor	1.000
Repeat	2	Correlation Offset	0.000
Number	5		
Concentration	*		
Interval	(...)		
Cut-off	No		
DUAL MODE			
Name	HbA1C	Low Absorbance	-0.100
Sample Blank	No	High Absorbance	3.000
R1 Bottle	25 mL	R. Abs. Low Limit	-0.100
Normal Volume	220 µL	R. Abs. High Limit	0.300
Rerun Volume	220 µL	Substrate Depletion	3.000
Sample		Reagent Blank	No
Normal Volume	8 µL	Cal. Low Limit	(...)
Rerun Volume	4 µL	Cal. High Limit	(...)
R2 Bottle	5 mL	Factor	
Normal Volume	40 µL		
Rerun Volume	40 µL	STD 1: Sodium Chloride 154 mmol/L (NaCl 0.9%)	
Predilution	No	STD 2: S1 STD 3: S2 STD 4: S3 STD 5: S4	
Slope Blank	No	... Data entered by the operator	
Point one, two	6,5 min.	(*) Enter the assigned value of standard S1-S4	

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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:

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