

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: SPECTRUM CCX

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 DEFINITION			
ENTRY NAME	HB	SAMPLE (mL) NORMAL	25
REPORT NAME	TOTAL HEMOGLOBIN	LOW	
RATIO REF.	HB	HIGH	
TEST NUMBER	***	UNITS PRIM	g/dL
TEST TYPE	AUX	SEC. UNIT FACTOR	
MATH	LIN REG END PT	PRINT DIGITS	0
REACTION DIRECTION	UP		
REAGENTS	2	INST MUL 1.000 INT 0.000	
TEMPERATURE	37	NORMAL (C)	... TO ...
TEST BLANK TYPE	REAGENT BLANK	SAMPLE DISP. DELAY (sec.)	0
LINEAR MODEL CALIBRATION DEFINITION			
TEST NAME	HB	TEST TYPE	AUX
CAL MODE	CAL ON CMD	MATH MODEL	LIN REG END PT
INTCPT TOL (C)	-1000.00 TO 1000.00	CAL INTERVAL (hr.)	720
% TOL OF CAL FACTOR	15	REF CAL FACTOR	***
CAL LEVEL	0	% TOL OF CAL	10
CALIBRATOR	LEVEL (C)	REPLICATES	
Std. 1	0.00	2	
Std. 2	(*) S4	2	
TEST PARAMETER FILE: REAGENT DEFINITION			
REAGENT NAME	HB	LINEARITY [C]	1.10 TO 40
REAGENT VOL (mL) NORM	236	INITIAL Ad	0.01
LOW	0.000	ABS LIMIT (Ad)	2.40
HIGH	236	REAGENT BLANK	
FIRST READ TIME (sec)	240	BEFORE WASH CYCLES	18
LAST READ TIME (sec)	240	AFTER WASH CYCLES	18
NUMBER OF READS	1	MIX TIME (sec)	1:00
READ INTERVAL (sec)	60	COOLING	YES
AUX REAG DISP (sec)	0	CONSTANT INTERCEPT	0.00
RSM	0	SPECTRAL CORRECTION	0.00
PRIM SEC USE IN CONST E.F. LOW HIGH	564 / 660 A 1.00 0.00 0.00 0.00		

... Data entered by the operator
Blank: Make reagent blank with sodium chloride 154 mmol/L.
(*) Enter the Standard S4 value

HBA1C

TEST DEFINITION									
ENTRY NAME	HBA1C		SAMPLE (mL) NORMAL				8.75		
REPORT NAME	HBA1C		LOW						
RATIO REF.	HBA1C		HIGH						
TEST NUMBER	***		UNITS PRIM				g/dL		
TEST TYPE	AUX		SEC. UNIT FACTOR						
MATH	LIN REG END PT		PRINT DIGITS				0		
REACTION DIRECTION	UP								
REAGENTS	2		INST MUL 1.000		INT 0.000				
TEMPERATURE	37		NORMAL (C)				... TO ...		
TEST BLANK TYPE	REAGENT BLANK		SAMPLE DISP. DELAY (sec.)				0		
LINEAR MODEL CALIBRATION DEFINITION									
TEST NAME	HBA1C		TEST TYPE				AUX		
CAL MODE	CAL ON CMD		MATH MODEL				LIN REG END PT		
INTCPT TOL (C)	-1000.00 TO 1000.00		CAL INTERVAL (hr.)				720		
% TOL OF CAL FACTOR	15		REF CAL FACTOR				***		
CAL . LEVEL	0		% TOL OF CAL				10		
CALIBRATOR	LEVEL (C)		REPLICATES						
Std. 1	0.000		2						
Std. 2	(*) S1		2						
Std. 3	(*) S2		2						
Std. 4	(*) S3		2						
Std. 5	(*) S4		2						
TEST PARAMETER FILE: REAGENT DEFINITION									
REAGENT NAME	HBA1C BUFFER		1 FOR TEST HBA1C				0.05 TO 2.50		
REAGENT VOL (mL) NORM	220		LINEARITY [C]				0.01		
LOW	0.000		INITIAL Ad				2.40		
HIGH	220		ABS LIMIT (Ad)						
FIRST READ TIME (sec)	180		REAGENT BLANK				18		
LAST READ TIME (sec)	180		BEFORE WASH CYCLES				18		
NUMBER OF READS	1		AFTER WASH CYCLES				1:00		
READ INTERVAL (sec)	60		MIX TIME (sec)				YES		
AUX REAG DISP (sec)	200		COOLING				0.00		
RSM	0		CONSTANT INTERCEPT				0.00		
PRIM	SEC	USE IN	CONST	E.F.	LOW	HIGH	SPECTRAL CORRECTION		
340	/	MA	A	1.00	0.00	0.00	0.00		
TEST PARAMETER FILE: REAGENT DEFINITION									
REAGENT NAME	HBA1C LATEX		2 FOR TEST HBA1C				0.05 TO 2.50		
REAGENT VOL (mL) NORM	45		LINEARITY [C]				0.1		
LOW	0.000		INITIAL Ad				3.00		
HIGH	45		ABS LIMIT (Ad)						
FIRST READ TIME (sec)	180		REAGENT BLANK				18		
LAST READ TIME (sec)	180		BEFORE WASH CYCLES				18		
NUMBER OF READS	1		AFTER WASH CYCLES				1:00		
READ INTERVAL (sec)	60		MIX TIME (sec)				YES		
AUX REAG DISP (sec)	0		COOLING				0.00		
RSM	0		CONSTANT INTERCEPT				0.00		
PRIM	SEC	USE IN	CONST	E.F.	LOW	HIGH	SPECTRAL CORRECTION		
340	/	MA	A	1.00	0.00	0.00	0.00		
(*) Calibrators 2-5: Standards S1-S4 ... Data entered by the operator									
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:

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