

# 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: **PRESTIGE 24i (=LABMAX 240, ZAPHYR 400)**

### 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**

Item Name	HB		CALIBRATION		LINEAR	
DATA INFORMATION	g/dL		Type	STANDARD		
Units	1		#1	0.0		
Decimal			#2	(*)		
ANALYSIS	END		NORMAL RANGE		MALE FEMALE	
Type	570		LOW HIGH		LOW HIGH	
Main W. Length 1	700		SERUM		URINE	
Main W. Length 2			CORR.			
Method	Slope		Y =		X +	
	1		0			
ASPIRATION	Double		DATA PROCESS		ABSORB LIMIT	
KIND	VOLUME		READ	START	END	
SAMPLE	30 µL		MAIN	30	32	Low 0
REAGENT 1 VOL	170 µL		SUB			High 2.5
REAGENT 2 VOL	µL		FACTOR		ENDPOINT LIMIT 2.5	
R1 Blank	Water Blank		Blank correction ---		LINEAR CHECK (%) 0	
Auto Rerun SW	On		Auto Rerun Condition (Absorbance)		Absorbance Range	
Auto Rerun Range(Result)	On		Lower On		Higher On	
	Lower Higher		Prozone Range Off			
Serum	1.1 40		Blank: Make reagent blank with sodium chloride 154 mmol/L			
Urine	---		(*) Calibrator: Standard S4			

**HbA1c**

Item Name	HBA1C				CALIBRATION					
DATA INFORMATION					Type	Logit-log 2				
Units	g/dL				STANDARD					
Decimal	2				#1	0.00	#4	(*) S3		
ANALYSIS					#2	(*) S1	#5	(*) S4		
Type	END				#3	(*) S2				
Main W. Length 1	340				NORMAL RANGE					
Main W. Length 2					MALE		FEMALE			
Method					LOW	HIGH	LOW	HIGH		
CORR.					SERUM	...	...	...	...	
Y =	Slope	X	+	Inter	URINE					
	1			0						
ASPIRATION					DATA PROCESS	ABSORB LIMIT				
KIND	Double				READ	START	END			
	VOLUME				MAIN	42	44	Low	0	
SAMPLE	8 µL				SUB	28	30	High	2.5	
REAGENT 1 VOL	200 µL				FACTOR				ENDPOINT LIMIT	2.5
REAGENT 2 VOL	40 µL				Blank correction				---	
R1 Blank	Water Blank				Third Mix.	OFF			LINEAR CHECK (%)	0
Auto Rerun SW	On				Auto Rerun Condition		(Absorbance)			
Auto Rerun Range(Result)	On				Absorbance Range		Lower	On		
	Lower Higher				Prozone Range		Higher	On		
Serum	0.05 2.50						Off			
Urine	---				STD 1: Sodium Chloride 154 mmol/L (NaCl 0.9%)					
...	Data entered by the operator				STD 2: S4	STD 3: S3	STD 4: S2	STD 5: S1		

Version 0706

**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:

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