

Hemoglobin A1c (HbA1c) Twin A1c Analyzer

REF: 602 001 50 test
Reagent1 2 x 10 ml
Reagent2 2 x 2 ml

Specimen Collection and Preparation

Fresh EDTA blood.

Hemolysate procedure

To determine HbA1c, a hemolysate must be prepared for each sample as follow:

1. Dispense 2 ml hemolysis reagent into a test tube.
 2. Place 20 µl of well mixed whole EDTA blood (Samples, Standards and Controls) into the test tube and mix.
 3. Allow to rest 5 minutes or until complete lysis is evident.
- Stability of the hemolysate: 72 hours at 2 - 8°C.

Procedure

- 1- Open the analyzer
- 2 - IN/ZB__PRS. ENTER (press Enter)
- 3- FOR__CALIBRATION (Left arrow For NO)
- 4 - Add 375 µ R1+5 µ LS (Lysing sample)
- 5 - Press enter (Wait for 120 Sec)
- 6 - Add 75 µ R2 & Press Enter (Wait for 303 Sec)
- 7- Press Right arrow To show the final result .
- 8 - Record the result.

Expected Values

Normal	< 6.0 %
Good control	6.0 – 6.8 %
Fair control	6.8 – 7.65 %
Poor control	> 7.65 %

Linearity

Up to 15 %.
specimens showing higher concentration should be diluted 1/5 using physiological saline and repeat the assay.










Reagent Preparation, Storage and Stability

Spectrum HbA1c reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when properly stored refrigerated at 2 – 8 °C. Once opened, the opened vial is stable for 1 months at the specified temperature.

Dynamic Range

0 - 15 %.

SYMBOLS IN PRODUCT LABELLING

	Authorised Representative		Temperature Limitation
	For in-vitro diagnostic use		Use by/Expiration Date
	Batch Code/Lot number		CAUTION. Consult instructions for use
	Catalogue Number		Manufactured by
	Consult instructions for use		

Waste Disposal

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.

S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Bates, H.M., Lab. Mang., Vol 16 (Jan. 1978)
2. Gonen, B., and Rubenstein, A.H., Diabetologia 15, 1 (1978).
3. Trivelli, L.A., Ranney, H.M., and Lai, H.T., New eng. J. Med. 284, 353 (1971).