



Hemoglobin A_{1c} (HbA_{1c}) (Glycosylated Haemoglobin) Twin A1c Analyzer

REF: 602 001 50 test

Reagent1 2 x 10 ml
 Reagent2 2 x 2 ml
 Hemolysis Reagent 2 x 50 ml
 Calibration card

Intended Use

Spectrum Diagnostics Hemoglobin A1c reagent is intended for Quantitative turbidimetric determination of HbA1c in human blood.

Reagent

Reagent1 (R1) (Avoid freezing)

Latex.
 Sodium azide (0.95 g/L).

Reagent2 (R2)

Anti-human hemoglobin A1c mouse monoclonal antibody.
 Stabilizers.

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 (**Avoid freezing**). Once opened, the reagent is stable for 1 month at the specified temperature.

Deterioration

The latex reagent should have a white, turbid appearance free of granular particulate. Visible agglutination or precipitation may be a sign of deterioration, and the reagent should be discarded. R2 reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarded.

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.

SYMBOLS IN PRODUCT LABELLING			
	Authorised Representative		Use by/Expiration Date
	For in-vitro diagnostic use		CAUTION. Consult instructions for use
	Batch Code/Lot number		Manufactured by
	Catalogue Number		(Xi) - Irritant
	Consult instructions for use		Temperature Limitation

Performance Characteristics

All the performance characteristics are found in the corresponding Technical Report and available on request

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.

Dynamic Range

0 - 15 %.

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).



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