Hemoglobin A_{1c} (HbA_{1c})
Turbidimetric Immunoassay

REF: 602 001- I	50 test	REF: 602 000 - I	25 test
Reagent1	2 x 10 ml	Reagent1	1 x 10 ml
Reagent2	2 x 2 ml	Reagent2	1 x 2 ml

Intended Use

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

Background

The glycemic control in diabetes mellitus is mainly by the determination of glucose, but also through quantitative determination of hemoglobin A1c in human blood. HbA1c is an indication for the actual glucose levels over the preceding 3 months. It was shown that HbA1c in diabetic subjects can be elevated 2-3 fold over normal and on other hand approaches normal values when they are under metabolic control.

Assay Principle

This method utilizes the interaction of antigen and antibody to determine th HbA1c in whole EDTA blood. HbA1c in test samples is absorbed onto the surface of latex particles, whiche react with Anti-HbA1c (antigen-antibody reaction)and gives agglutination. The amount of agglutination is measured as absorbance. The HbA1c value is obtained from a calibration curve.

Reagent

Reagent1 (R1) **(Avoid freezing)**
Latex.
Sodium azide (0.95 g/L).

Reagent2 (R2)
Anti-human hemoglobin A1c mouse monoclonal antibody.
Stabilizers.

Materials required but not provided with the kit

1- Standard set
HbA1c concentration is stated on the vials labels.

2-Controls

Reagent Preparation, Storage and Stability

Spectrum HbA1c reagents are stable up to the expiry date labeled on the bottles when stored at 2 - 8^{o}C **(Avoid freezing)** and contaminations are prevented during their use.Once opened the reagents are stable for 1 month if stored tightly closed at 2 - 8 ^{o}C after use.

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 ml 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 hemosylate: 72 hours at 2 - 8^{o}C.

Procedure

Wavelength	650 nm
Temperature	37 ^{o}C
Cuvette	1cm light path
Zero adjustment	distilled water

Solve and lyse standard/control

SYMBOLS IN PRODUCT LABELLING

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

	Standard	Sample
Reagent (R1)	375 ul	375 ul
Standard	5 ul	-----
Sample	-----	5 ul
Mix, and incubate for 2 minutes, then add		
Reagent (R2)	75 ul	75 ul

Mix and read absorbance (**A1**) immediately, then **after 5 minutes** read absorbance **(A2).**

Adaptation sheets for several automatic analyzers are available upon request.

Calculation

Generate a reference curve using HbA1c standard set. Determine D absorbance of the sample and each standard as following:
D absorbance of sample = (A2 - A1) sample
D absorbance of each standard = (A2 - A1) for each Standard
Plot the calibration curve and obtain the result.

Expected Values

Non-diabetics < 6 %
Theraputic diabetics < 7 %
Each laboratory should establish its own reference range.

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).

ORDERING INFORMATION

CATALOG NO.	QUANTITY
602 000 - I	25 test
602 001 - I	50 test

Egyptian Company for Biotechnology (S.A.E)
Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.
Tel: +202 4489 2248 - Fax: +202 4489 2247
www.spectrum-diagnostics.com
E-mail:info@spectrum-diagnostics.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

CE

ISO 13485:2016