Spectrum For Diagnostic Industries

IVD

HbA1c Turbidimetric Immunoassay

Cat. No.	Pack size
132 02 10	50 tests

Intended Use

Hemoglobin A1c reagent is intended for quantitative turbidimetric determination of HbA1c in human blood .

Introduction

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.

Method

ImmunoTurbidimetry

Principle

This method utilizes the interaction of antigen and antibody to determine the HbA1c in whole EDTA blood. HbA1c in test samples is absorbed onto the surface of latex particles, which 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.

Reagents

Reagent 1
Latex.
Sodium azide 0.95 g/L.

Reagent 2
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

Reagents preparation, storage and stability

HbA1c reagents are stable till the expiration date labeled on the bottles when stored at 2 - 8^{O}C and contaminations are prevented during their use.Once opened the reagents are stable for 1 month if stored tightly closed at 2 - 8 ºC after use.

Deterioration

Failure to recover control values within assigned range may indicate reagent deterioration

Precautions and warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Specimen collection and preservation

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^{O}C.

Procedure

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

Solve and lyse standard/control

	Standard	Specimen
Reagent (R1)	375 µl	375 µl
Standard	5 µl	-----
Specimen	-----	5 µl

Mix, and incubate for 2 minutes, then add

Reagent (R2)	75 µl	75 µl

Mix and read absorbance (A1), incubate for 5 minutes and read absorbance (A2)

Adaptation sheets for several automatic analyzers are available upon request.

Calculation

Generate a reference curve using HbA1c standard set. Determine

Absorbance of the sample and each standard as following:
Absorbance of sample = (A2 - A1) sample
Absorbance of each standard = (A2 - A1) for each standard
Plot the calibration curve and obtain the result.

Quality control

Normal and abnormal control serum of known concentration should be analyzed with each run.

Linearity

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

Interference

Bilirubin
No significant interference up to 15 mg/dL Bilirubin

Glucose
No significant interference up to 4000 mg/dL glucose .

Lipemia
No significant interference up to 3000 mg/dL Intralipid.

Expected Values

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

Performance Characteristics

A study using 20 human specimens between this HbA1c reagent and reference method yielded a correlation coefficient of 0.998 and a linear regression equation of y = 1.060x + 0.037

Precision
Within run (Repeatiblity)

	Level 1	Level 2
n	20	20
Mean (%)	5.4	14.8
SD	0.05	0.12
CV%	0.93	0.93

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (%)	5.4	14.8
SD	0.051	0.11
CV%	0.94	0.80

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).

SYMBOLS IN PRODUCT LABELLING

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

Spectrum For Diagnostic Industries - Free Zone
Ismailia Free Zone, Block 5 .
Cairo- Port said Avenue.
Ismailia,Egypt
Tel: +2 064 3488 013 - +2 064 3488 014 Fax: +2 064 3488 015
www.sdi-fz.com

EC REP MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

CE

ISO 13485:2016