

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 A_{1c} reagent is intended for Quantitative turbidimetric determination of HbA_{1c} in human blood.

Background

The glycemic control in diabetes mellitus is mainly by the determination of glucose, but also through quantitative determination of hemoglobin A_{1c} in human blood. HbA_{1c} is an indication for the actual glucose levels over the preceding 3 months. It was shown that HbA_{1c} 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 HbA_{1c} in whole EDTA blood. HbA_{1c} in test samples is absorbed onto the surface of latex particles, whiche react with Anti-HbA_{1c} (antigen-antibody reaction)and gives agglutination. The amount of agglutination is measured as absorbance. The HbA_{1c} value is obtained from a calibration curve.

Reagent

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

Reagent2 (R2)
 Anti-human hemoglobin A_{1c} mouse monoclonal antibody.
 Stabilizers.

Materials required but not provided with the kit

1- Standard set
 HbA_{1c} concentration is stated on the vials labels.

2-Controls

Reagent Preparation, Storage and Stability

Spectrum HbA_{1c} reagents are stable up to the expiry date labeled on the bottles when stored at 2 - 8°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 °C after use.

Specimen Collection and Preparation

Fresh EDTA blood.

Hemolysate procedure

To determine HbA_{1c}, 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

Wavelength 650 nm
 Temperature 37 °C
 Cuvette 1cm light path
 Zero adjustment distilled water

Solve and lyse standard/control

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

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

Mix, and incubate for 2 minutes, then add

Reagent (R2) 75 µl 75 µl

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 HbA_{1c} 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 %
 Therapeutic 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 %.

Performance Characteristics

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

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

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