Hemoglobin A_1c direct

Immunoturbidimetric latex

CE IVD for in vitro use

REF 10456 - 130 test

Kit for the determination of Hemoglobin A1c (HbA1c) in human blood. Direct turbidimetric method - 2 reagents

PRINCIPLE

This method utilizes the interaction of antigen and antibody to directly determine the HbA1c in whole blood. Total hemoglobin and HbA1c have the same unspecific absorption rate to latex particles. When mouse antihuman HbA1c monoclonal antibody is added (R2), latex-HbA1c-mouse anti human HbA1c antibody complex is formed. Agglutination is formed when goat anti-mouse IgG polyclonal antibody interacts with the monoclonal antibody. The amount of agglutination is proportional to the amount of HbA1c absorbed on to the surface of latex particles. The amount of agglutination is measured as absorbance. The HbA1c value is obtained from a calibration curve.

REAGENTS

R1 Latex 0.13%, Glycine buffer 20mmol/L.
R2a Glycine buffer 80mmol/L
R2b Mouse anti-human HbA1c monoclonal antibody 0.05mg/ml, goat anti-mouse IgG polyclonal antibody 0.08mg/dl, stabilizers.

REAGENT PREPARATION

R1 is liquid and ready to use. R2 is prepared by pouring the entire contents of the R2b vial into the R2a vial. Mix gently.

REAGENTS STORE AND DETERIORATION

Store all reagents refrigerated at 2-8°C
All reagents are stable to the expiration date stated on the labels. Do not use the reagents past their expiration date.
R1 and R2 are stable for at least one month after opening stored at 2-8°C
Hemoglobin A1c in whole blood collected with EDTA is stable for one week at 2-8°C.5
Alterations in the physical appearance of the reagents or values of control materials outside of the manufacturer's acceptable range may be an indication of reagent instability.

PRECAUTIONS

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). The total concentration of components is lower than the limits reported by 67/548 and 88/379 CE Regulations (and following modifications) about classification, packaging and labelling of dangerous substances.
However the reagent should be handled with caution, according to good laboratory practice.

NOTE

In case of complaint or quality control request, refer to the lot number on the package or the lot number on the singles vials.

SPECIMEN COLLECTION AND PREPARATION

Collect venous blood with EDTA using aseptic technique. All human specimens should be regarded as potentially bio hazardous. Therefore, universal precautions should be used in specimen handling (gloves, lab garments, avoid aerosol production, etc.).
To determine HbA1c, a hemolysate must be prepared for each sample:
- Dispense 1ml Hemolysis Reagent into tubes labelled: Control, Patients etc.
- Place 20ul of well mixed whole blood into the appropriately labelled lyse reagent tube. Mix.
- Allow to stand for 5 minutes or until complete lyses is evident. Hemolysates may be stored up to 10 days at 2-8°C.

PROCEDURE

Refer to specific instrument application for suggested settings.

MATERIALS REQUIRED BUT NOT PROVIDED

Lysing reagent (10452), calibrators (HbA1c Standard Set ref. 20126), controls (ref. 20127).

EXPECTED VALUES

Non-diabetic	HbA_1c	< 6%
under treatment Diabetic	HbA_1c	< 7%

Each laboratory should establish its own expected values. In using Hemoglobin A1c to monitor diabetic patients, results should be interpreted individually. That is, the patient should be monitored against him or herself. There is a 3-4 week time lag before Hemoglobin A1c reflects changes in blood glucose level.

PERFORMANCE

A study using 40 human specimens between this Hemoglobin A1c procedure and an automated HPLC procedure (Tosoh) yielded a correlation coefficient of 0.988 and a linear regression equation of y=1.05x – 0.481. Syx = 0.332)

Linearity: The Hemoglobin A1c assay range is 2.0%-16.0%.

intra assay precision	Media	DS	CV %
Low	5.48	0.078	1.43
High	10.28	0.176	1.72

inter assay precision	Media	DS	CV %
Low	5.48	0.152	2.77
High	11.28	0.275	2.68

INTERFERENZE

Bilirubin to 50mg/dL, ascorbic acid to 50mg/dL, triglycerides to 2000mg/dL, carbamylated Hb to 7.5mmol/L and acetylated Hb to 5.0mmol/L do not interfere in this assay.
It has been reported that results may be inconsistent in patients who have the following conditions: opiate addiction, lead-poisoning, alcoholism, ingest large doses of aspirin.

REFERENCES

T. Trivelli, L.A.Raney , H.M and Lai H.T New Eng J Med 284,353 (1971)
Gonen ,B. and Rubenstein, AH. Diabetologia 15, 1 (1978)
Gabbay, K.H. Hasty, K.Breslow, J.L., Elison R.C., Bun.H.F. and Gallop, P.M. J Clin. Endocrinol. Metab 44, 859,(1977)
Bates, H.M. Lab Mang. Vol 16 (Jan 1978).

SIMBOLOGY

Read instruction for use

CE mark (requirement of 98/79 regulation)

Storaging temperature limits

IVD **In vitro medical device**

Producer

Hemoglobin A_1c direct

Immunoturbidimetric latex

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APPLICATION NOTE
HITACHI 917

Instrument setting

TEST	[HA1C]		
ASSAY CODE	[1Point]	[50]	[50]
WAVELENGHT	[660]		
S. VOL (Regular)		[5]	[3]
ABSORB LIM		[32000]	[Increase]
PROZONE LIM		[--]	[--]
REAGENT	R1	[180]	[50]
R2	[60]	[20]	
CALIBRATION	[NON LINEAR]	[4]	[5]
STD (1) CONC POS		[*]	[1]
STD (2) CONC POS		[**]	[2]
STD (3) CONC POS		[**]	[3]
STD (4) CONC POS		[**]	[4]
STD (5) CONC POS		[**]	[5]
STD (6) CONC POS		[-]	
SD LIM		[999]	
DUPLICATE LIM		[1000]	
SENSITIVITY LIM		[0]	
PROZONE LIMIT		[-]	[-]
PANIC VALUE		[-]	[-]
INSTRUMENT FACTOR	[1.0]		
EXPECTED VALUES	[-]	[-]	

* Use saline solution for Calibrator 0.0

** Insert the value of each calibrator