TECO DIAGNOSTICS
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Hemoglobin A1C Set
FOR TC MATRIX SYSTEMS

INTENDED USE
For the quantitative determination of Hemoglobin A1c (HbA1c) in human blood on TC MATRIX analyzers.

INTRODUCTION
Throughout the circulatory life of the red cell, Hemoglobin A1c is formed continuously by the adduction of glucose to the N-terminal of the hemoglobin beta chain. This process, which is non-enzymatic, reflects the average exposure of hemoglobin to glucose over an extended period. In a classical study, Trivelli et al showed Hemoglobin A1c in diabetic subjects to be elevated 2-3 fold over the levels found in normal individuals. Several investigators have recommended that Hemoglobin A1c serve as an indicator of metabolic control of the diabetic, since Hemoglobin A1c levels approach normal values for diabetics in metabolic control. Hemoglobin A1c has been defined operationally as the "fast fraction" hemoglobins (HbA_{1a}, A_{1b}, A_{1c}) that elute first during column chromatography with cation-exchange resins. The non-glycosylated hemoglobin, which consists of the bulk of the hemoglobin has been designated HbA_0. The present procedure utilizes a antigen and antibody reaction to directly determine the concentration of the HbA1c.

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), latexHbA1c-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. The TC MATRIX System automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio is one part sample to 94 parts reagent. The system monitors the change in absorbance at 650 nanometers. This change in absorbance is directly proportional to the concentration of HbA1c in the sample and is used by the TC MATRIX System to calculate and express HbA1c concentration.

REAGENTS
Each kit contains: One HbA1c Reagent 1 (30 ml)
One HbA1c Reagent 2 (10 ml)

Two Hemolysis liquid reagents (2x100 ml)
Instruction Insert
Application for TC MATRIX analyzers.

REAGENT PREPARATION
Reagent 1, Reagent 2 and Hemolysis reagents are supplied as ready to use liquids. Mix gently before use.

REAGENT COMPOSITION
Latex: 0.13%
Glycine buffer: 20mmol/L.
Mouse anti-human HbA1c monoclonal antibody: 0.05 mg/ml
Goat anti-mouse IgG polyclonal antibody: 0.08 mg/dl, stabilizers.
Also non-reactive chemicals for optimal system performance.

REAGENT STORAGE AND STABILITY
Teco HbA1c Reagent 1, Reagent 2 and Hemolysis reagentsstored unopened at 2ºC to 8ºC are stable until the expiration date showed on the respective bottle labels. DO NOT FREEZE.

SPECIMEN COLLECTION AND HANDLING
1. Special preparation of the patient is unnecessary. Fasting specimens are not required. No special additives or preservatives other than anticoagulants are required. Collect venous blood with EDTA using aseptic technique. All human specimens should be regarded as potentially biohazardous. Therefore, universal precautions should be used in specimen handling (gloves, lab garments, avoid aerosol production, etc.).
2. To determine HbA1c, a hemolysate must be prepared for each sample:
   1) Dispense 1ml Hemolysis Reagent into tubes labeled: Control, Patients, etc. Note: Plastic or glass tubes of appropriate size are acceptable.
   2) Place 20µL of well mixed whole blood into the appropriately labeled lyse reagent tube. Mix well.
   3) Allow standing for 5 minutes or until complete lyses is evident. Hemolysates may be stores up to 10 days at 2-8°C.

PROCEDURE

TEST NAME:	HbA1c	R1:	180
TEST NO.		R2:	60
FULL NAME:	HbA1c	SAMPLE VOLUME:	5
REFERENCE NO.:		R1 BLANK:	/
ANALY.TYPE:	End-Point	MIX REAG. BLANK:	
PRI. WAVE :	670nm	CONCENTRATION:	/
SECON. WAVE:	-	LINEARITY LIMIT:	2-16%
TREND:	Increase	SUBSTRATE LIMIT:	/
REACT. TIME:	1-24	FACTOR:	/
INCUBATE TIME:	19	PROZONE CHECK:	/
UNIT:	%	Q1: / Q2: / Q3: / Q4: /	
PRECISION:	Integer	PC: /ABS.: /	
CALIBRATION TYPE: Calibrate+Reag.Blank		CALIBRATION RULE: Spline	

CALCULATIONS
1. Calibrator required: Teco HbA1c Calibrators.
2. The system must have a valid calibration in memory before controls or patient samples can be run.
3. Under typical operating conditions Teco HbA1c Reagent cartridge must be re-calibrated every 7 days.
4. The TC MATRIX system will automatically perform checks on the calibration and produce data at the end of the calibration.

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT
1. Teco Hemoglobin A1c calibrator set.

2. Teco Hemoglobin A1c control set.

LIMITATIONS

1. This assay should not be used for the diagnosis of diabetes mellitus
2. Patient specimens should always be assayed using a calibration curve.
3. 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.
4. It has been reported that elevated levels of HbF may lead to underestimation of HA1c and, that uremia does not interfere with HbA1c determination by immunoassay.
5. It has been reported that Hemoglobin variants HbS and HbA2 are not detected by immunoassay, leading to possible inaccurate determination. Also it has been reported that labile intermediates (Schiff base) are not detected and therefore, do not interfere with HbA1c determination by immunoassay.
6. Other very rare variants of hemoglobin (e.g. HbE) have not been assessed.

INTERFERENCE

1. Bilirubin to 50mg/dL, ascorbic acid to 50mg/dL, triglycerides to 2000mg/dL, carbamylatedHb to 7.5mmol/L and acetylated Hb to 5.0mmol/L do not interfere in this assay.
2. 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.
3. It has been reported that elevated levels of HbF may lead to underestimation of HA1c and that uremia does not interfere with HbA1c determination by immunoassay.
4. It has been reported that Hemoglobin variants HbS and HbA2 are not detected by immunoassay, leading to possible inaccurate determination. Also, it has been reported that labile intermediates (Schiff base) are not detected and do not interfere with HbA1c determination by immunoassay.[5]

EXPECTED VALUE

Recommended Values: less than 6% for a non-diabetic, less than 7% for glycemic control of a person with diabetes.

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.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Since all specimens are potentially infections, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to safety precautions of such materials.
3. Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.

PROCEDURES

Use open channel and follows the attached parameters and procedures to perform the tests.

PERFORMANCE CHARACTERISTICS

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

Comparison: A study using 25 human specimens between this Hemoglobin A1c procedure and another automated immunoassay procedures (Roche Diagnostics) yielded a correlation coefficient of 0.9952 and a linear regression equation of y=1.04x + 0.27. (SEOE = 0.43)

Precision:

Within Run: The intra assay precision was established by assaying blood with three Hemoglobin A1c levels twenty times each.

Level	Mean	Std. Dev.	% C.V.
Low	4.75	0.07	1.26
Medium	7.30	0.08	1.10
High	10.9	0.16	1.46

Run To Run: The inter run precision was established by assaying three blood samples in duplicate with different Hemoglobin A1c levels for ten runs conducted over a five day period.

Level	Mean	Std. Dev.	% C.V.
Low	4.73	0.06	1.27
Medium	7.35	0.09	1.09
High	11.0	0.16	1.51

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