ISE S.r.l.
CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

HbA1c (100 test) – Instructions for use

IVD

R1: 1 x 18,5 mL R2: 1x 3,4 mL LYS: 2x16 mL **R3330000001** REF

Intended Use
The determination of HbA1c is most commonly performed for the evaluation of glycemic control in diabetes mellitus. HbA1c values provide an indication of glucose levels over the preceding 4-8 weeks. A higher HbA1c value indicates poorer glycemic control.

Diagnostics Implications
Throughout the circulatory life of the red cell, HbA1c is formed continuously by the adduction of glucose to the N-terminal of the hemoglobin beta chain. The process, which is non-enzymatic, reflects the average exposure of haemoglobin to glucose over an extended period. In a classical study, Trivelli et al showed HbA1c in diabetic subjects to be elevated 2-3 folds over the levels found in normal individuals. Several investigators have recommended that HbA1c serves as an indicator of metabolic control of the diabetic, since HbA1c levels approach normal values for diabetics in metabolic control. 2,3,4
HbA1c has been defined operationally as the "fast fraction" hemoglobins (HbA1a, A1b, A1c) 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 HbA0.

Method
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.

Kit R1: 1 x 18,3 mL R2: 1 x 3,3 mL code R3330000001
Reagent 1: no. 1 Vials x 18.3 mL Ready to Use
Reagent 2: no. 1 vials x 3,3 mL Ready to Use

Reagents Provided

Reagent 1:		
	Conc.	**U.M.**
Latex	4.00	%
Sodium Azide	0.95	g/L
Reagent 2:		
Anti-humanEmoglobin A1c Mouse Mon	-	-
Stabilizers.	-	-
Reagent 3:		
Lise Solution. Stabilizers.	-	-

Preparation and Stability of Reagents
Reagent Preparation
R1, ready for use.
R2, ready for use.
Lysing solution, ready for use.

Stability and Storage
The reagents are stable until expiry date when kept at 2-8°C. After opening the reagents are stable for 1 month at 2-8°C.

Reagents required but not supplied
1. Calibrators and Controls*

Key Reference	**Description**
R0300000003	Hemoglobin A1c Standard Set
R0400000007	Hemoglobin A1c Control Low
R0400000004	Hemoglobin A1c Control High

*Hemolysates from packed human erythrocytes lyophilized and stabilized. Values are stated in the insert.

Sample collection and preparation
Use fresh EDTA blood. To determine HbA1c, a hemolysate must be prepared for each sample:
Dispense 2 mL Hemolysis Reagent into a test tube. Place 20 µL of well mixed whole EDTA blood (samples, standards and controls) into the test tube. Mix. Allow to rest for 5 minutes or until complete lysis is evident.
Stability of the hemolysate: 72 hours at 2-8 °C.

General Assay Procedure
Application sheets for automated systems on clinical chemistry analyzers or manual procedures are available upon request.
Wavelength 578 nm

Procedure
Quality control
Human control serum with known levels of HbA1c is commercially available for quality control purposes. Data sheets are included, listing the values and the confidence limits. Normal and abnormal control sera are available from I.S.E. S.r.l. "Low control" code R0400000007 and "High control" code R0400000004. Obtained values must be within the range of acceptability. If erratic results occur, the following points should be checked:
- Cleanliness of glassware.
- Wavelength setting.
- Expiration date of reagents.

Automation
This kit, though developed and manufactured to be used as manual assay and with I.S.E. S.r.l. analyzer, can be used also with other analyzers able to meet the specifications indicated in section "Reaction conditions - Test procedure" Application sheets are available for automatic instruments.
All applications not explicitly approved by I.S.E. S.r.l. cannot be guaranteed in terms of performance, and must therefore be established by the operator.

Calibration Stability
For the instrumentation series Hemo One, the calibration is recommended to be done every 15 days.

Conversion Formulas
Method NGSP unit: %HbA1c = 0.0915*(Res in mmol/mol) + 2.15%
Method IFCC unit: mmol/mol =10.93*(Res in %) – 23.5mmol/mol

NORMAL VALUE
- Non Diabetics: < 6% (42.1) mmol/mol
- Therapeutic Diabetics:< 7% (53.1) mmol/mol

Each laboratory should calculate its own normal values on the basis of its local population

ANALYTICAL CHARACTERISTICS / PERFORMANCE
0 - 15 %/L,.

Specificity
Under the conditions of the assay system this method is specific for HbA1c.

Accuracy-Recovery

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The recovery of pure HbA1c added to normal sample at known titter was 101.7%.

Precision of the method

Precision				
		Low	Medium	High
Inter Run	CV%	1.42	0.90	1.49
Intra Run	CV%	0.79	0.73	0.88
Accuracy				
Control	U.M.	Measured	Assigned	
Low	%/L	5.58	5.1 – 6.9	
High	%/L	13.47	11.8 – 16.0	

Sensitivity
At λ 578 nm a concentration of about Measuring Range: 0 – 16 % (0 - 151.38) mmol/mol

Comparative method
The I.S.E. S.r.l. method was compared to a method in use.
Comparison with ISE, 138C012:
y = 1.0823x – 0.1887 / r = 0.9828
Stability at 2 - 8°C: at least 2 years after production

Disposal of reagent
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

The product is in conformity with D.L: 8 September 2000, no. 332 "Actuation of the directive 98/79/EC regarding in vitro medical diagnostic devices".

Symbols on labels and packaging

IVD = In vitro diagnostic medical device

REF = Catalog Number

LOT = Lot Number

= Manufacturer

= Expiration date

= Temperature limitation

= Instruction for use

References
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