

## Reagents for STAT LAB T Analyzer & Auto Chemistry Analyzer

### HbA1c kit

REF: 401 001 **50 Tests**      REF: 401 002 **250 Tests**  
 R1: 1 x 7.8 ml                      R1: 1 x 38 ml  
 R2: 1 x 2.7 ml                      R2: 1 x 12.8 ml  
 Lysing                                      Lysing  
 Calibrator 4 level                      Calibrator 4 level

#### Intended Use

The glycemc control in diabetes mellitus is performed mainly by the determination of Glucose, but also through quantitative determination of Hemoglobin A1c (HbA1c) in human blood.

#### Background

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 the other hand approaches normal values when they are under metabolic control.

#### Test 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 4 point calibration curve.

#### Reagents

(R1) Latex. Sodium azide (0.95 g/L).

(R2) Anti-human hemoglobin A1c mouse monoclonal antibody and Stabilizers.

#### Calibrator

4 different levels of calibrators and 0.1% sodium-azide.  
Assigned Value: Stated on Calibrator Label.

(LR) Lysing Reagent.

#### Storage and Stability

Store all reagents refrigerated at 2-8°C. Unopened reagents are stable up to the expiration date printed on the labels. Opened vials are stable for one month

#### Additional Reagents

Control Set available upon request.

#### Specimen Collection and Preparation










Collect venous blood with EDTA using aseptic technique. To determine HbA1c, a hemolysate must be prepared for each sample

1. Dispense 1 mL of (LR) into patient tubes
2. Place 10µL of well mixed whole blood into the Appropriately labeled tube. Mix thoroughly.
3. Allow to stand for 5 minutes, store up to 10 days 2-8°C.

#### Precautions

1. The reagent is for in vitro diagnostic use only.
2. Reagents are liquid stable, ready-to-use reagents.
3. Mix by inverting at least 10 times before use.
4. Do not mix reagents of different lots.
5. **DO NOT FREEZE.**
6. 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.)

#### SYMBOLS IN PRODUCT LABELLING

	Authorized 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		

#### Procedure:

Wavelength                              700 nm  
 Method                                      fixed rate  
 Temperature                              37 °C

	Calibrator	Sample
R1 (µL)	150	150
Calibrator(µL)	10	-
Sample (µL)	-	10
<b>Mix and incubate for 5 min at 37°C.</b>		
R2(µL)	50	50

Mix then read absorbance (A1) after 10 seconds, at 700 nm. After 5 minutes, read (A2) and calculate ΔAbs.

#### Calculation

Calculate the Abs of Calibrators.

$$\Delta\text{Abs} = A_2 - A_1$$

Plot the ΔAbs of each calibrator versus assigned concentration.

Then HbA1c concentration of the sample is calculated by interpolation of ΔAbs on the calibration curve.

#### Expected Values

(%) DCCT / NGSP  
 4.0 – 6.0 Non Diabetic  
 6.0 – 6.5 Mean  
 6.5 – 8.0 Good Control

#### Conversion from HbA1c % to mmol/mol

HbA1c %	HbA1C mmol/mol
6.0	42
6.5	48
7.0	53
7.5	59
8.0	65
9.0	75
10	86

#### Note:

Each laboratory should establish its own expected values. The given values can only be an average indication.

#### Limitations

1. Results may be inconsistent in patients e.g. with opiate addiction, lead-poisoning, alcoholism, ingestion of large doses of aspirin.
2. Elevated levels (> 10%) of HbF may lead to underestimation of HA1c.
3. Hemoglobin variants HbS, HbC and HbE do not interfere in this assay.

- There is also no interference by labile intermediates, and uremia does not interfere too.

## Performance Characteristics:

### Dynamic Range:

The Hemoglobin A1c assay range is 3.0% to 16.0%. Results in this range can be reported and used directly.

### Linearity: up to 15 %

### Correlation:

A study using 40 human specimens between this procedure and the reference method yielded a correlation coefficient of 0.9874 and a linear regression equation of  $y = 1.021x + 0.014$

### Precision:

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

<u>Level</u>	<u>Mean</u>	<u>% C.V.</u>
Medium	5.7	1.0
High	10.3	0.7

## Interferences:

- Bilirubin to 15mg/dL, ascorbic acid to 10mg/dL, triglycerides to 3000mg/dL, Glucose to 4000mg/dL, carbamylated Hb to 5mmol/L and acetylated Hb to 5.0mmol/L do not interfere in the assay.
- It has been reported that results may be inconsistent in patients who have the conditions like opiate addiction, lead-poisoning, alcoholism, ingestion of large doses of aspirin.

## References

- Trivelli, L.A., Ranney, H.M., and Lai, H.T., New Eng. J. Med. 284,353 (1971).
- Gonen, B., and Rubenstein, A.H., Diabetologia 15, 1 (1978).
- Gabbay, K.H., Hasty, K., Breslow, J.L., Ellison, R.C., Bunn, H.F., and Gallop, P.M., J. Clin. Endocrinol. Metab. 44, 859 (1977).
- Bates, H.M., Lab. Mang., Vol 16 (Jan. 1978).
- Tietz, N.W., Textbook of Clinical Chemistry, Philadelphia, W.B. Saunders Company, p.794-795 (1999).
- Coriello, A., et al, Diabetologia 22, p. 379 (1962).
- Goldstein, D.E., et al, Clin. Chem. 32, pp. 364-370 (1986).
- Fluckiger, R., et al, Med Intelligence 304 pp. 823-827 (1981).
- Nathan, D.M., et al, Clin. Chem. 29, pp. 466-469 (1983).
- American Diabetes Association: Clinical Practice Recommendations, Diabetes Care 24 (Suppl. 1):



**Egyptian Company for Biotechnology (S.A.E)**

Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.

Tel: +202 4489 2248 - Fax: +202 4489 2247

[www.spectrum-diagnostics.com](http://www.spectrum-diagnostics.com)

E-mail: [info@spectrum-diagnostics.com](mailto:info@spectrum-diagnostics.com)



**MDSS GmbH**  
Schiffgraben 41  
30175 Hannover, Germany



IFUFT171

Rev(1), 1/12/2021