

# Nephchem Glycated Hemoglobin A1c (Nephelometry method)



| KIT NAME         | KIT SIZE | CAT. NO    |
|------------------|----------|------------|
| Nephchem - HbA1C | 25 Tests | NA1C01025T |

## INTRODUCTION

Glycated Hemoglobin A1c (HbA1c) is intended for Invitro quantitative determination of HbA1c in human whole blood. Hemoglobin A1c is a subtype of hemoglobin A that is formed by a non-enzymatic process that adducts glucose to the N-terminal of the hemoglobin beta chain. This process reflects the average hemoglobin exposure to glucose over an extended period and provides clinical significance in monitoring the blood glucose level. Studies have shown HbA1c in diabetic patients to be 2-3 times the levels found in normal individuals. HbA1c can be used as an indicator of metabolic control of the diabetic.

## METHOD PRINCIPLE

The kit utilizes latex-enhanced immunoturbidimetry to measure the HbA1c level in human whole blood by GB NEPHCHEM (Nephelometry method) The Kit utilizes the antibody-antigen reaction to directly measure the HbA1c level in whole blood. The first reaction, occurring after the sample is mixed with R1, consists of unspecified binding of total hemoglobin and HbA1c to the latex particles at the same rate. The second reaction occurs after the addition of R2 that contains mouse anti-human monoclonal antibody and goat anti-mouse IgG polyclonal antibody. Agglutination complexes will be formed from the interaction of the HbA1c bound to the latex particles with the respective antibodies. GB NEPHCHEM, analyzer. The agglutination can be measured as an absorbance which is proportional to the amount of HbA1c bound to the latex, and because the total hemoglobin and HbA1c bind to the latex at the same rate, the % HbA1c in total hemoglobin can be obtained from a calibration curve

## KIT CONTENTS

| Reagent kit - box   |             |
|---------------------|-------------|
| R1 - Hba1C latex    | 1x 4.9 ml   |
| R2 - Hba1c antibody | 1 x 1.6 ml  |
| R3 - Lysing reagent | 1 x 6.75 ml |
| Test Card           | 1 no        |
| Accessories kit box |             |
| Cuvettes            | 25 nos      |
| Big tips            | 25 nos      |
| small tips          | 50 nos      |
| PCR (bullet vial)   | 25 nos      |

## Working reagent preparation and stability

Reagent R1 and R2 are ready to use liquid stable at 2-8°C till the expiry date printed on the package.

## Concentrations in the test

R1 - Latex 0.1%; Glycine buffer, pH 3.0, 15mmol/L

R2 - goat anti-mouse IgG polyclonal antibody 0.8mg/dl; Mouse anti-human HbA1c monoclonal antibody 0.05 mg/ml; Glycine buffer, pH 3.0, 60mmol/L

R3 - H2O2, stabilizers

## Warnings and notes

- The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
- The instructions must be followed to obtain accurate results.
- Do not use the reagents beyond the expiration date.
- Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

## SPECIMEN

The Test can be performed with human blood without special preparation of the patient. Follow standard laboratory procedures to collect specimens with EDTA.

## HEMOSYLATE STEP:

- Mix 250 µl of Hemolysis Reagent with 5 µl of well mixed whole blood
- Wait for 5 minutes or until complete lysis is evident before using the sample.

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- If immediate testing is not possible, hemolysates may be stored up to 10 days at 2-8°C.

## PROCEDURE

**It is very important for antigen-antibody reaction needs the pre-warm of both reagents and samples. Along with GB NEPHCHEM equipment, dry bath incubator will be provided, in that dedicated R1, R2 and sample positions were available. Please use the respective positions for desired pre-warm temperature of 37°C**

**Step 1: Insert Test Card to Card reader slot and display will show promptly add R1 + S (sample)**

**Step 2: Pipette out 180 µl of R1 into dedicated cuvette and add 5 µl of sample (hemolysated sample) and place the cuvette in the reading chamber**

**Step 3: After the incubation, the display will show promptly add R2**

**Step 4: Pipette out 60 µl of R2 using sensor pipette connected with machine into the cuvette**

**Step 5: Once the reaction time got over, the result will show in the display and (if external printer connected then it will get print out)**

## REFERENCE VALUES

|                      |                       |
|----------------------|-----------------------|
| HbA1c in whole blood | < 6% Non-diabetic     |
|                      | < 7% Glycemic Control |

It is recommended for each laboratory to establish its own reference ranges for local population.

## QUALITY CONTROL

To ensure adequate quality control, each kit can be cross checked with commercially available third party Immunological quality control or use recommended GB Immunology Quality control.

## PERFORMANCE CHARACTERISTICS

- Linearity:** 2% to 14%
- Precision:** within Run CV ≤ 5 %
- Specificity / Interferences**

No interference detected for bilirubin upto 0.5 g/L ascorbic acid 0.5 g/L, triglycerides 20 g/L, carbamylated Hb 7.5 mmol/L and acetylated Hb 5.0 mmol/L

## WASTE MANAGEMENT

Please refer to local legal requirements.

## LITERATURE

- American Diabetes Association: Clinical Practice Recommendations (Position Statement). Diabetes Care 24 (Suppl. 1): S33-S55, (2001).
- Bates, H.M., Lab. Mang., Vol 16 (Jan. 1978).
- Ceriello, A., et al, Diabetologia 22, p. 379 (1982).
- Engbaek, F., et al, Clin. Chem. 35, pp. 93-97 (1989).
- Fluckiger, R., et al, New Eng.J. Med. 304 pp. 823-827 (1981).
- Gabbay, K.H., Hasty, K., Breslow, J.L., Ellison, R.C., Bunn, H.F.,



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