Nephchem Apolipoprotein B
(Nephelometry method)

KIT NAME	KIT SIZE	CAT. NO
Nephchem - Apo B	25 Tests	NAPB01025T

GENUINE BIOSYSTEM

INTRODUCTION

Apolipoprotein B (Apo B) is intended for Invitro quantitative determination of Apo B in human serum. Apolipoprotein B (APO B) is the major protein component of low density lipoprotein (LDL). It enables the reaction with LDL receptors in the liver and on cell walls and transports cholesterol from the liver to tissue cells. Studies have shown APO B to have a direct relationship to coronary artery disease and an inverse relationship with APO A1. APO B levels are useful in assessment of cardiovascular risk in addition to LDL cholesterol levels. Elevated levels of APO B can be an indication of increased cardiovascular risk even when total cholesterol and LDL cholesterols are within the normal range.

METHOD PRINCIPLE

The kit utilizes latex-enhanced immunoturbidimetry to measure the Apo B level in human serum by GB NEPHCHEM (Nephelometry method). TThe Kit utilizes immunoturbidimetry to measure the APO B level in human serum. During the test, APO B in the sample binds with the specific anti-APO B antibody to cause agglutination. The turbidity caused by agglutination is detected optically GB NEPHCHEM, analyzer. The change in absorbance is proportional to the level of APO B in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations

KIT CONTENTS

Reagent kit - box	
R1 - Apo B buffer	1 x 4.9 ml
R2 - Apo B antibody	1 x 1.6 ml
Test Card	1 no
Accessories kit box	
Cuvettes	25 nos
Big tips	25 nos
small tips	50 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 - Glycine buffer solution. Sodium azide < 0.1%
R2 - anti-APO B antibodies, glycine buffer, sodium azide < 0.1%

Warnings and notes
1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
5. Samples containing levels of APO B above the assay range should be diluted with saline and retested.
6. Reagents contain less than 0.1% sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

SPECIMEN

Follow standard laboratory procedures to collect serum samples. It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2-4° C for up to 3 days or at -20° C for up to 6 months. Avoid repeated freezing and thawing.

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 (serum) 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

60 to 110 mg/dL

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:** 30 to 200 mg/dL
- **Precision:** within Run CV ≤ 4 %
- **Specificity / Interferences**
  No interference detected for bilirubin upto 60 mg/dL and hemoglobin 10 g/L, triglycerides 1000 mg/dL

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

1. Raz, A., et al, J. Biol. Chem. 244: 12 (1969).
2. Kottke BA, et al. Mayo Clin. Proc. 1986; 61: 313.
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5. Sandkamp M. Diagnose & Labor 1990; 40: 37.

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