Nephchem Immunoglobulins M (IgM)
(Nephelometry method)

KIT NAME	KIT SIZE	CAT. NO
Nephchem - IgM	25 Tests	NIGM01025T

INTRODUCTION

Immunoglobulin A (IgM) is intended for Invitro quantitative determination of IgM in human serum. Immunoglobulin M is the first immunoglobulin to appear in response to antigenic challenge and makes up about 5 to 10% of the total circulating immunoglobulins. IgM is particular effective in combating bacterial infections because of its high binding affinity for proteins responsible for destroying bacterial cells. IgM levels increase due to viral infections, rheumatoid arthritis, chronic hepatocellular disease, active sarcoidosis, Waldenstrom's macroglobulinemia, and malignant lymphoma. Decreased levels of IgM are associated with recurrent, chronic, or severe infections, multiple myeloma, and protein-losing enteropathy.

METHOD PRINCIPLE

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

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KIT CONTENTS

Reagent kit - box	
R1 - IgM buffer	1x 4.9 ml
R2 - IgM 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 - Phosphate buffer, Polyethylene glycol, Sodium azide < 0.1%
R2 - anti-IgM antibodies, Tris 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. 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 1 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

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GENUINE BIOSYSTEM

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

40 to 230 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:** 0 to 500 mg/dL
- **Precision:** within Run CV ≤ 6 %
- **Specificity / Interferences**
  No interference detected for bilirubin upto 60 mg/dL and hemoglobin 500 mg/dL

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Consensus of a Group of Professional Societies and Diagnostic Companies on Guidelines for Interim Reference Rangesfor 14 Proteins in Serum Based on the Standardization against the IFCC/BDR/CAP Reference Material (CRM 470). EurJ Clin Chem Biochem 1996:34;517-520.
2. Houghton Mifflin Company, 2004. "Immunoglobulin M." The American Heritage Dictionary of the English Language, Fourth Edition. Accessed on 12 Oct. 2007.
3. Ritchie, RF (ed). Serum Proteins in Clinical Medicine, Volume 1, Laboratory Section. Scarborough, ME: Foundation for Blood Research; 11.01-7; 1996.
4. Tietz NW, Pruden E, McPherson RA, Fuhrman, SA (eds). Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Co; 361-363; 1995

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