Nephchem Immunoglobulins A (IgA)
(Nephelometry method)

KIT NAME	KIT SIZE	CAT. NO
Nephchem - IgA	25 Tests	NIGA01025T

GENUINE BIOSYSTEM

INTRODUCTION

Immunoglobulin A (IgA) is intended for Invitro quantitative determination of IgA in human serum. Immunoglobulin A (IgA) accounts for 10 to 15% of serum immunoglobulin. IgA plays a critical role in muscosal immunity and is found to be at high levels in the gastrointestinal system, genitourinary system and respiratory system. IgA measurement is used to diagnose diseases of the respiratory tract, monitor IgA myeloma and evaluate IgA immunity. Increase in IgA levels can be due to recurrent infections, anaphylactic transfusion reactions, chronic liver disease, chronic infections, neoplasia of the lower GI tract, and inflammatory bowel disease. Decreased levels of IgA may be found in isolated genetic deficiency, combined immunodeficiency disorders, non-IgA multiple myeloma or macroglobulinemia

METHOD PRINCIPLE

The kit utilizes latex-enhanced immunoturbidimetry to measure the IgA level in human serum by GB NEPHCHEM (Nephelometry method). The Kit utilizes immunoturbidimetry to measure the IgA level in human serum. During the test, IgA in the sample binds with the specific anti-IgA 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 IgA 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 - IgA buffer	1x 4.9 ml
R2 - IgA 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-IgA 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.

GBPL/NCIGA/02 9.19

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

72 to 429 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 670 mg/dL
- **Precision:** within Run CV ≤ 6 %
- **Specificity / Interferences**
  No interference detected for bilirubin upto 60 mg/dL and hemoglobin 10 g/L

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Burtis C, Ashwood, ER (ed). Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia, P; WB Saunders Co; 509; 1999.
2. Junqueira, Luiz C.; Jose Carneiro (2003). *Basic Histology*. McGraw-Hill.
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4. Tietz NW, Pruden E, McPherson RA, Fuhrman, SA (eds). Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Co; 355–357; 1995.

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