Nephchem Immunoglobulins E (IgE)
(Nephelometry method)

KIT NAME	KIT SIZE	CAT. NO
Nephchem - IgE	25 Tests	NIGE01025T

GENUINE BIOSYSTEM

INTRODUCTION
IgE is an immunoglobulin with a molecular weight of approximately 190,000Da and is normally present in the blood in trace amounts. IgE antibodies are the chief immunoglobulin responsible for immediate hypersensitivity reactions in humans

METHOD PRINCIPLE
The kit utilizes latex-enhanced immunoturbidimetry to measure the IgE level in human serum by GB NEPHCHEM (Nephelometry method). The Kit utilizes immunoturbidimetry to measure the IgE level in human serum. During the test, IgE in the sample binds with the specific anti-IgE 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 IgE 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 - IgE buffer	1x 4.1 ml
R2 - IgE antibody	1 x 2.05 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-IgE antibodies, Phosphate 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

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

Step 2: Pipette out 150 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 75 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

Less t han 1 year old	1.35 - 19.5	IU/mL
1 -3 yrs	5.24 - 30.0	IU/mL
4 -6 yrs	5.20 - 112.0	IU/mL
6 - 9 yrs	13.12 - 142.0	IU/mL
10 - 12 yrs	11.20 - 172.0	IU/mL
13 - 18 yrs	25.00 - 126.00	IU/mL
> 19 yrs	28.00 - 140.0	IU/mL

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:** 3 to 1000 IU/mL
- **Precision:** within Run CV $\leq$ 6 %
- **Specificity / Interferences**
  No interference detected for bilirubin upto 25 mg/dL and hemoglobin 10 g/L, Triglycerides 1000 mg/dL

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE
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