Nephchem C Reactive Protein
(Nephelometry method)

KIT NAME	KIT SIZE	CAT. NO
Nephchem - CRP	25 Tests	NCRP01025T

INTRODUCTION

C Reactive Protein (CRP) is intended for Invitro quantitative determination of C Reactive protein in human serum or whole blood. CRP is an acute-phase reactant that reflects low grade systemic inflammation. In response to an inflammatory stimulus, a rise in CRP level up to 1000 fold may be detected within 6 hours.CRP is sensitive but the increase in CRP is non-specific, thus interpretation of CRP value should be complimented by complete clinical history. CRP measurements may also be performed for early detection of infection in paediatrics and risk assessment of coronary heart disease.

METHOD PRINCIPLE

The kit utilizes latex-enhanced immunoturbidimetry to measure the CRP level in human serum by GB NEPHCHEM (Nephelometry method) During the test, CRP in the sample binds with the specific anti-CRP antibody that is coated on latex particles 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 CRP in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

KIT CONTENTS

Reagent kit - box	
R1 - CRP buffer	1 x 6.5 ml
R2 - CRP 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 - Latex suspension, anti-CRP 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. 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- 8° C for up to 5 days or at -20° C for up to 6 months.
Avoid repeated freezing and thawing.

GENUINE BIOSYSTEM

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 240 µl of R1 into dedicated cuvette and add 5 µl of sample (serum or whole blood) 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

upto 6.0 mg/L

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:** 0.3 to 150 mg/L
- **Precision:** within Run CV ≤ 6 %
- **Specificity / Interferences**
  No interference detected for bilirubin upto10 mg/dl, hemoglobin upto 500mg/dl,

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Osmond, A.P., et al, Proc. Natl. Acad. Sci. 74:739-743, 1977.
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6. Wasunna A, et al. C-reactive protein and bacterial infection in preterm infacnts. Eur J Pediatr 1990; 149: 424-427.

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Genuine Biosystem Private Limited
Plot No.97 & 98, kattabomman street,
Parvathy Nagar Extension,
Old Perungalathur, Chennai - 600063, India.
Ph: +91-44-48681845
Email: genuinebiosystem@gmail.com
website: www.genuinebiosystem.com