Nephchem Rheumatoid Factor
(Nephelometry method)

KIT NAME	KIT SIZE	CAT. NO
Nephchem - RF	25 Tests	NRF001025T

GENUINE BIOSYSTEM

INTRODUCTION

Rheumatoid Factor (RF) is intended for Invitro quantitative determination of Rheumatoid Factor in human serum. Rheumatoid Factors (RF) are heterogeneous group of high molecular weight auto-antibodies of immunoglobulin isotypes IgM, IgA, IgG, and IgE. They are produced by plasma cells present at sites of issue injury, and may play a role in the regulation of humoral and cellular immunity and protection against invading microorganisms though the exact function of RF remains unclear. Studies have shown that both environmental and genetic factors can affect the synthesis of RF. RF levels are often elevated in patients with rheumatoid arthritis and Sjogren's syndrome, and could also rise in scleroderma, dematomyositis, Waldenstrom's disease, sarcoidosis, and systemic lupus erythematosus.

METHOD PRINCIPLE

The kit utilizes latex-enhanced immunoturbidimetry to measure the RF level in human serum by GB NEPHCHEM (Nephelometry method) During the test, RF in the sample binds with the specific human anti-RF gamma-globulin 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 RF 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 - RF buffer	1 x 6.5 ml
R2 - RF 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 - Buffer solution, sodium azide < 0.1%
R2 - latex particles coated with human gamma-globulin, 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 240 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

upto 20.0 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:** 6.0 to 150 IU/ml
- **Precision:** within Run CV ≤ 6 %
- **Specificity / Interferences**
  No interference detected for bilirubin upto 60 mg/dl, hemoglobin upto 1000mg/dl

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Ritchie, RF (ed). Serum Proteins in Clinical Medicine, Volume 1 Laboratory Section. Scarborough, ME: Foundation for Blood Research; 11.06.02-1; 1996.
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3. Tietz NW, Pruden E, McPherson RA, Fuhrman, SA (eds). Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA:WB Saunders Co; 544-545; 1995.

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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