

# Nephchem Complement C4 (Nephelometry method)



KIT NAME	KIT SIZE	CAT. NO
Nephchem - C4	25 Tests	NCC401025T

## INTRODUCTION

Complement C4 (C4) is intended for Invitro quantitative determination of C4 in human serum. Complement component 4 (C4) is a protein of the complement system. It is activated in the classical pathway which leads to the formation of the C3 convertase. C4 plays vital role in tissue cell damage and inflammation in immunologic disorders. Decreased levels of C4 may be the result of systemic lupus erythematosus (SLE), hereditary angioedema, autoimmune hemolytic anemia, and autoimmune nephritides. Conversely, C4 levels increases in a variety of inflammatory and necrotic disorders as part of the acute-phase plasma protein response.

## METHOD PRINCIPLE

The kit utilizes latex-enhanced immunoturbidimetry to measure the C4 level in human serum by GB NEPHCHEM (Nephelometry method). The Kit utilizes immunoturbidimetry to measure the C4 level in human serum. During the test, C4 in the sample binds with the specific anti- C4 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 C4 in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

## KIT CONTENTS

Reagent kit - box	
R1 - C4 buffer	1x 4.9 ml
R2 - C4 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-C4 antibodies, Tris buffer, sodium azide < 0.1%

## Warnings and notes

- The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
- The instructions must be followed to obtain accurate results.
- Do not use the reagents beyond the expiration date.
- Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
- 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 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

17 to 48 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 64.0 mg/dL
- Precision:** within Run CV ≤ 6 %
- Specificity / Interferences**  
No interference detected for bilirubin upto 60 mg/dL and hemoglobin 10 g/L, triglycerides 1000 mg/dL

## WASTE MANAGEMENT

Please refer to local legal requirements.

## LITERATURE

- Burtis C, Ashwood, ER (ed). Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia, PA; WB Saunders Co; 506; 1999.
- Liu CC, Manzi S, Kao AH, Navratil JS, Ruffing MJ, Ahearn JM (2005). "Reticulocytes bearing C4d as biomarkers of disease activity for systemic lupus erythematosus". *Arthritis Rheum.* 52 (10): 3087-99.
- Wouters D, Wiessenberg HD, Hart M, et al. Complexes between C1q and C3 or C4; novel and specific markers for classical complement pathway activation. *J Immunol Methods*, 2005, 298 (1-2); 35-45.



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