

Nephchem Cystatin C (Cys-C) (Nephelometry method)



KIT NAME	KIT SIZE	CAT. NO
Nephchem - Cystatin-C	25 Tests	NCYS01025T

INTRODUCTION

Cystatin C (Cys-C) is intended for Invitro quantitative determination of Cys-C in human serum. Cystatin C is a small cysteine proteinase inhibitor produced by all nucleated cells that can be freely filtered by the glomerular membrane and then nearly completely reabsorbed and degraded by the renal tubular cells. Thus, plasma concentration of cystatin C can be used as an indicator of glomerular filtration rate (GFR). Cystatin C levels are less dependent on age, sex, race and muscle mass compared to creatinine, making it a better assessment for kidney functions.

METHOD PRINCIPLE

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

KIT CONTENTS

Reagent kit - box	
R1 - Cys-C buffer	1 x 6.5 ml
R2 - Cys-C 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

R2 - Latex particles coated anti-Cys C antibodies

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.

SPECIMEN

Follow standard laboratory procedures to collect serum or heparin plasma 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 2 days or at -20° C for up to 6 months. Avoid repeated freezing and thawing. **Do not use haemolysed samples.**

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

0.57 to 1.12 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 to 8.0 mg/L
- Precision:** within Run CV ≤ 8%
- Specificity / Interferences**
No interference detected for bilirubin upto 18.6 mg/dL, ascorbic acid 500 g/L, triglycerides 1000 mg/dL, hemoglobin 460 mg/dL and Rheumatoid factor 240 U/ml

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

- A V Lewis, T J James, J B J McGuire and R P Taylor. Improved immunoturbidimetric assay for cystatin C. *Ann Clin Biochem* 2001; 38: 111 – 114
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