

**Reagent kit for quantitative estimation of Cystatin C in Serum.**

**DIAGNOSTIC SIGNIFICANCE:**

Cystatin C is a nonglycosylated 13-kDa basic protein belonging to the cystatin super-family of cysteine proteinase inhibitors. Cystatin C is produced by virtually all nucleated cells, and is present in all investigated body fluids. The production rate is constant and unaffected by inflammatory processes, sex, age, diet and nutritional status. In the normal kidney, Cystatin C is freely filtered through the glomerular membrane of the nephron and then nearly completely reabsorbed and degraded by the proximal tubular cells. Therefore, the plasma concentration of Cystatin C is almost exclusively determined by the GFR (glomerular filtration rate), making Cystatin C an excellent indicator of GFR. At the same time Cystatin C is becoming acknowledged as a marker of elevated risk of death from cardiovascular complications – myocardial infarction and stroke.

**PRINCIPLE:**

This Cystatin C test is based upon the reactions between Cystatin C and latex-covalently bound antibodies against human Cystatin C.

**SPECIMEN COLLECTION:**

Fresh or deep-frozen Serum. Cystatin C remain stable for 12 days. At 2-8°C. If the test should be performed later, it is recommended to freeze the serum. Avoid successive freezing and thawing. Discard haemolysed or contaminated samples.

**KIT PRESENTATION:**

PACK SIZE	1 X 24 ml	1 X 48 ml
R1- Cystatin C (Buffer Reagent)	1 X 20 ml	1 X 40 ml
R2- Cystatin C (Latex Reagent)	1 X 04 ml	1 X 08 ml
Cystatin C Calibrator	1 No	1 No

**REAGENT PREPARATION:**

Cystatin C Reagent and Calibrator ready to use.

**REAGENT STORAGE AND STABILITY:**

All reagents and calibrator included in the kit are stable at 2-8°C until the expiry date stated on the label.

**NOTE:** Bring the reagent and calibrator at Room Temperature before use.

**SPECIFICITY-INTERFERENCES:**

No significant interference by haemoglobin or bilirubin. Other substances may interfere.

**ASSAY PARAMETERS:**

Reaction : Fix Time	Sample Volume : 06 µl
Wavelength : 546 nm	Reagent 1 Volume : 500 µl
Flow Cell Temp. : 37°C	Reagent 2 Volume : 100 µl
Initial Delay : 05 Sec	Calibrator Conc. : As per Vial
Read Time : 300 Sec	Zero Setting : Dist. Water
Reaction Slope : Increasing	Linearity : 10 mg/L

**PROCEDURE:** Bring the Reagent and Calibrator at R.T. before use.

Pipette into TT	Calibrator	Test
R1-Cystatin C (Buffer Reagent)	500 µl	500 µl
R2-Cystatin C (Latex Reagent)	100 µl	100 µl
Cystatin C Calibrator	6 µl	--
Sample (Test)	--	6 µl

Mix & aspirate immediately and read difference in absorbance between 05 seconds (AT<sub>1</sub>) and 300 seconds (AT<sub>2</sub>) for Calibrator and Test at 546 nm.

**CALCULATION:**

$$\text{Cystatin C (mg/L)} = \frac{\Delta\text{Abs of Test} \times \text{Cocn. of Calibrator}}{\Delta\text{Abs of Calibrator}}$$

Where  $\Delta\text{Abs} = (\text{AT}_2) - (\text{AT}_1)$

**NORMAL VALUES:**

Normal Value : 0.59 – 1.03 mg/L

Each laboratory must establish its own expected range. Results should be interpreted considering all other test results and the clinical situation of the patient.

**LINEARITY:**

Up to 10 mg/L

**Limit of detection:** < 0.05 mg/L.

**Sensitivity:** 54.8 mAbs/(mg/L)

**Prozone effect:** not at least up to 16 mg/L

**REFERENCES:**

1. Mutsumi Tanaka, Kenje Matsuo, Masayasu Enomoto and Koji Mizuno. A Sol particle homogeneous immunoassay for measuring serum cystatin C. *Clin. Biochem.* 37 (2004) 27 – 35.
2. Davis Massey. Commentary: Clinical Diagnostic Use of Cystatin C. *Journal of Clinical Laboratory Analysis* 18:50 – 60 (2004).
3. Michael G. Shlipak and al. Cystatin C and the risk of Death and cardiovascular events among elderly persons. *NEJM* 2005 volume352:2049-2060.

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Expiry Date



In-Vitro Diagnostics Use



Storage



Mfg. Date



Batch Number



Catalogue Number



See Package Insert