TURBICHEM CYSTATIN-C

(Turbidimetry)

KIT NAME	KIT SIZE	CAT. NO
Turbichem - Cystatin - C	1 x 50 ml	TCYS00050M

GENUINE BIOSYSTEM

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 cystain 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 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 chemistry 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

R1 - Cys - C Buffer	1 x 40 ml
R2 - Cys - C Antibody	1 x 10 ml
R3 - Cys - C Calibrator	1 vial

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 10 days on board the analyser at 2-10°C. Protect from light and avoid contamination.

WORKING REAGENT PREPARATION AND STABILITY

Assay can be performed with use of separate R1-Cys-C and R2-Cys-Creagents of 4 parts of R1-Cys-C with 1 part of R2-Cys-C. Avoid foaming.

CONCENTRATIONS IN THE TEST

R1 - Glycine buffer solution
R2 - Latex particles coated anti-Cys C antibodies

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

ADDITIONAL EQUIPMENT

- Automatic analyzer or photometer able to read at 546 nm
- Thermostat at 37ºC
- General laboratory equipment

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

PLOTTING OF MULTIPOINT CURVE

The Turbichem Cystanin-C is based on Non-Linear Reactions, hence it is strongly recommended to run Multi-standard mode to plot the Multi-point curve to have better accuracy and precise result.

Serial Dilution Step

	1st	2nd	3rd	4th	5th
Calibrator	100 µl	50 µl from 1st Tube	50 µl from 2nd Tube	50 µl from 3rd Tube	50 µl from 4th Tube
Normal Saline	0	50 µl	50 µl	50 µl	50 µl
Ratio of Dillution	Neat	1/2	1/4	1/8	1/16

PROCEDURE

These reagents may be used both for manual assay and in several automatic analyzers. Applications for them are available on request.

Wavelength 546 nm
Temperature 37°C
Cuvette 1 cm

Pipette into the cuvette:

Reagent	Calibrator (C)	Test (T)
R1 Cys-C Buffer	800 µl	800 µl
Calibrator	15 µl	
Sample	-	15 µl
Bring up to the temperature of determination. Than add		
R2 - Cys-C Anitbody	200 µl	200 µl

Mix well, after about 10 sec. (37°C) read the absorbance A1 of the test (T) and calibrator (C) against air or water.After exactly 300 secs. (for all temperature) read the absorbance A2 of the test (T) and calibrator (C). Calculate ΔA/min. (A2 - A1) for the test and calibrator.

CALCULATION

Cystanin-C concentration = ΔA (T) / ΔA(C) x calibrator concentration

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 run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls.

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.
- **Reagent Blank Absorbance:** at 570nm wavelength and 10mm optical diameter, O.D. ≤ 1. 50

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. 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
2. Dharnidharka VR, Kwon C, Stevens G (August 2002). J. Kidney Dis. 40(2): 221–6.
3. Köttgen A, Selvin E, Stevens LA, Levey AS, Van Lente F, Coresh J (March 2008). Serum cystanin C in the United States. The third national health and nutrition survey J. Kidney Dis. 51(3): 385–94.
4. Mutsumi Tanaka, Kenje Matsuo, Masayasu Enomoto and KojiMizuno. A Sol particle homogeneus immunoassay for measuring serum cystatin C. Cli. Biochem. 37(2004)27 – 35.
5. Roos JF, Doust J, Tett SE, Kirkpatrick CM (March 2007).in. Biochem. 40(5-6): 383–91.
6. Stevens LA, Coresh J, Schmid CH, et al. (March 2008). Estimating GFR using serum cystanin C alone and in combination with serum creatinine: a pooled analysis of 3418 individuals with CKD Am. J. Kidney Dis. 51(3): 395–406

SYSTEM PARAMETERS

Method	Fixed Time (2-Point)
Wavelength	546 nm
Zero Setting	Distilled Water
Temperature Setting	37° C
Incubation Temperature	37° C
Incubation Time	----
Delay Time	10 secs
Read Time	300 secs
No. of Reading	2
Interval Time	----
Sample Volume	0.015 ml (15 ul)
Reagent Volume	1.0 ml (1000 ul)
Standard Concentration	Refer Calibrator vial
Units	mg/dl
Factor	----
Reaction Slope	Increasing
Linearity	8.0 mg/dl

IVD CE

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