Cat. No 9-462

DIAGNOSTIC KIT FOR DETERMINATION OF CYSTATIN C CONCENTRATION

OS – CYSTATIN C

INTRODUCTION
Cystatin C is a low molecular weight protein (13kD), one of the cysteine proteinases inhibitors. Cystatin C is produced in all nucleated cells and secreted into extracellular space at constant rate. Cystatin C molecule stability and dependence of its concentration solely on GFR (Glomerular Filtration Rate) decide about high diagnostic efficiency of cystatin C determination. Cystatin C level is not affected by muscle mass or diet and its increase is observed even at slight GFR reduction. Clinical applications of cystatin C are for monitoring GFR in children, elderly patients, patients with potentially nephrotoxic drug therapy, for assessment of renal transplantation status, for kidney function monitoring in acute and chronic kidney diseases including diabetic nephropathy.

METHOD PRINCIPLE
Turbidimetric method. An antigen-antibody reaction occurs between cystatin C and antibodies coated on polystyrene particles and immuno-complexes are formed. The change of turbidity is related to the quantity of cystatin C in the sample.The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of know concentration.

REAGENTS
Package

1-Reagent	1 x 35.5 ml
2-Reagent	1 x 10 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 9 weeks on board the analyser at 2-10°C. Protect from light!

Concentrations in the test

suspension of polystyrene particles coated with anti-cystatin C antibodies	8.5 g/l
MOPS buffer [3-(N-morpholino)-propanesulfonic acid]	8 g/l
sodium azide	15 mmol/l
gentamycin	12.5 mg/l
amphotericin B	1.25 mg/l

Warnings and notes
- Product for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- The reagents contain antibiotics and must be handled with due cautions.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN
Human serum or EDTA/heparinised plasma. It is recommended to analyse the samples as fresh as possible. Sample stability testing showed that cystatin C in serum and plasma samples are stable for 14 days at room temperature (8-25ºC) and for 21 days if stored at 2-8ºC, otherwise store frozen at below -20ºC. Mix samples well before analysing. The samples can be shipped without special cooling and must then be analysed within 14 days after shipment.

PROCEDURE
These reagents may be used in automatic analysers Olympus AU400/AU640.
1-Reagent and 2-Reagent are ready to use.
For reagent blank 0.9% NaCl is recommended.

APPLICATION
Reagent ID: **511**

Specific Test Parameters — General | LIH | ISE | Range

Test name: **CysC** Type: **Serum** Operation: **Yes**

Sample:	Volume	2	µL	Dilution	0	µL	Pre-Dilution Rate:	1	
Reagents:	R1 Volume	150	µL	Dilution	0	µL	Min OD	Max OD	
	R2 Volume	30	µL	Dilution	10	µL	L -2.0000	H 2.5000	
							Reagent OD Limit:		
Wavelength:	Pri.	540		Sec.	None		First L -2.0000	First H 2.5000	
Method:		END					Last L -2.0000	Last H 2.5000	
Reaction Slope:		+					Dynamic Range:		
Measuring Point 1:	First	13		Last	27		L 0.14	H 8.5	
Measuring Point 2:	First			Last			Correlation Factor:		
Linearity:			%				A 1.000	B 0.000	
No-Lag-Time:							On-board Stability Period:		

Specific Test Parameters — General | LIH | ISE | Range

Test name: **CysC** Type: **Serum**

Value/Flag: # Level L: # Level H: #

Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
1.	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#
7. None Selected						#	#
8 Out of Range						#	#

Panic Value: L # H # Unit: **mg/l** Decimal Places: **2**

Calibration Specific — General | ISE

Test name: **CysC** Type: **Serum**

Calibration Type: **7AB** Formula: **SPLINE** Counts: **1** Process: **CONC**

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		**	-2.0000	2.5000
Point 2:	#		*	-2.0000	2.5000
Point 3:	#		*	-2.0000	2.5000
Point 4:	#		*	-2.0000	2.5000
Point 5:	#		*	-2.0000	2.5000
Point 6:	#		*	-2.0000	2.5000
Point 7:	#		*	-2.0000	2.5000

1-Point Cal.Point: with CONC-0 Slope Check: **None** Advanced Calibration: #

MB Type Factor: Calibration Stability Period:

\# User defined
* Calibrator value
** Saline should be used as calibrator 1

REFERENCE VALUES

serum, plasma	mg/l
adults	0.5 – 1.2
children (0.2 – 18 yr)	0.7 – 1.4

It is recommended for each laboratory to establish its own reference ranges for local population. Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

QUALITY CONTROL
For internal quality control it is recommended to use the CORMAY CYSTATIN C CONTROLS (Cat. No 4-460) with each batch of samples.
For the calibration of automatic analysers the CORMAY CYSTATIN C CALIBRATORS (Cat. No 5-185) is recommended. The calibration curve should be prepared every 9 weeks, with change

of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS
These metrological characteristics have been obtained using the automatic analysers Olympus AU400, BS-400 and Modular P. Results may vary if a different instrument is used.

- **Sensitivity:** 0.14 mg/l.

- **Linearity:** up to 8.5 mg/l.

- **Specificity / Interferences**

Haemoglobin up to 0.7 g/dl, bilirubin up to 800 mg/l, triglycerides up to 14 g/l and ascorbate up to 300 mg/l do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [mg/l]	SD [mg/l]	CV [%]
level 1	0.81	0.01	1.10
level 2	3.37	0.02	0.71

Reproducibility (day to day) n = 20	Mean [mg/l]	SD [mg/l]	CV [%]
level 1	0.878	0.024	2.727
level 2	5.245	0.230	4.384

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 21 samples gave following results:
y = 1.3091 x - 0.295 mg/l;
R = 0.9977 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

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Date of issue: 06. 2011.

MANUFACTURER

PZ CORMAY S.A.
22 Wiosenna Street,
05-092 Łomianki, POLAND
tel.: +48 (0) 22 751 79 10
fax: +48 (0) 22 751 79 14
http://www.cormay.pl

06/11/06/11