# 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

# 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.</li>
   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 (8-25°C) and for 21 days if stored at 2-8°C, otherwise store frozen at below -20°C. 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.

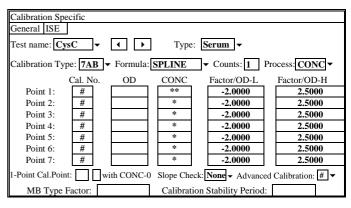
For reagent blank 0.9% NaCl is recommended.

# CE CORMAY

## APPLICATION

Reagent ID: 511 Specific Test Parameters Range LIH ISE General **←** Test name: CysC Type: Serum ▼ Operation: Yes ▼ Sample: Volume μL Dilution 0 μL Pre-Dilution Rate: 1 Reagents: R1 Volume 150 μL Dilution μL Min OD μL Dilution 10 R2 Volume 30 L -2.0000 H 2.5000 Reagent OD Limit: Pri. **540** ▼ First L -2.0000 First H 2.5000 Wavelength: Sec. None Method: END Last L -2.0000 Last H 2.5000 Reaction Slope: Dynamic Range: L 0.14 Measuring Point 1: First 13 Last H 8.5 Measuring Point 2: First Last Correlation Factor: Linearity: A 1.000 В 0.000 No-Lag-Time On-board Stability Period:

Specific Test Para General LIH		gg							
General   LIH   ISE   Range   Test name:   CysC   ▼									
Value/Flag: # ▼ Level L: # Level H: # Normal Ranges:									
J	Age L	Age l		_					
Sex	Year Mont		Month	L	Н				
1. # ▼	# #	#	#	#	#				
2. # ▼	# #	#	#	#	#				
3. # ▼	# #	#	#	#	#				
4. # ▼	# #	#	#	#	#				
5. # ▼	# #	#	#	#	#				
6. # ▼	# #	#	#	#	#				
7. None Selected # #									
8 Out of Range # #									
L H									
Panic Value:	#		#	Unit: mg/l	Decimal Places: 2				



- # 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

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

Reproducibility (day to day)	Mean	SD	CV
n = 20	[mg/l]	[mg/l]	[%]
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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