Cystatin C FS*

Order Information

Cat. No.	Kit size				
1 7158 99 10 930	R1	4 x 12 mL	+	R2	2 x 8 mL

Intended Use

Diagnostic reagent for quantitative in vitro determination of cystatin C in human serum or heparin plasma on automated photometric systems.

Summary

Cystatin C is a non-glycosylated, basic protein with a low molecular weight of 13 kDa. It acts as a cysteine protease inhibitor, is endogenously produced at a constant rate by all nucleated cells investigated and freely filtered by the glomerular membrane before being almost completely reabsorbed and degraded in the renal tubuli. Cystatin C is suggested to be a better marker for detection of reduced glomerular filtration rate (GFR) than creatinine especially for the detection of a moderate impairment of kidney function. The cystatin C blood level is, in contrast to creatinine, is less dependent on factors such as sex, muscle mass and age. Cystatin C determination may be useful especially in children, elder people, in diabetics, in patients with liver cirrhosis, in adult renal transplant recipients, in cancer patients and in pregnant woman suspected of preeclampsia. [1-9]

Method

Particle enhanced immunoturbidimetric test

Determination of cystatin C concentration by photometric measurement of antigen antibody reaction between antibodies against cystatin C bound to polystyrene particles and cystatin C present in the sample.

Reagents

Components and Concentrations

R1:	TRIS	pH 7.5	100 mmol/L
	NaCl		200 mmol/L
R2:	Borate		7.5 mmol/L
	Monoclonal antibodies (mouse) against human cystatin C bound to carboxylated polystyrene particles		< 1%

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Protect from light.

Warnings and Precautions

1. Reagent 1 contains sodium azide (0.9 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 2 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. The reagents contain animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
4. In very rare cases, samples of patients with gammopathy might give falsified results [10].
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
6. For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

The reagents are ready to use.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Stability [11]:

2 days	at	20 – 25°C
1 week	at	2 – 8°C
1 month	at	–20°C

Only freeze once. Discard contaminated specimens.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	596 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	1.0 µL
Reagent 1	90 µL
Reagent 2	30 µL
Addition reagent 2	Cycle 19 (286 s)
Absorbance 1	Cycle 22/23 (327 s/340 s)
Absorbance 2	Cycle 41/42 (586 s/600 s)
Calibration	Spline

Calculation

The cystatin C concentration of unknown samples is derived from the calibration curve using an appropriate mathematical model such as logit/log or spline. The calibration curve is obtained with five calibrators at different levels and NaCl solution (9 g/L) for determination of the zero value.

Calibrators and Controls

DiaSys TruCal Cystatin C calibrator set is recommended for calibration. Calibrator values have been made traceable to the IFCC reference material ERM®-DA471. Use DiaSys TruLab Cystatin C Level 1 and Level 2 for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Cystatin C	1 7150 99 10 059	5 x 1 mL
TruLab Cystatin C Level 1	5 9870 99 10 046	3 x 1 mL
TruLab Cystatin C Level 2	5 9880 99 10 046	3 x 1 mL

Performance Characteristics

Data evaluated on BioMajesty® JCA-BM6010/C

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 8 mg/L, depending on the concentration of the highest calibrator. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.	
Limit of detection**	0.2 mg/L
No prozone effect up to 30 mg/L.	

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [mg/L]
Bilirubin (conjugated)	50 mg/dL	0.451
	50 mg/dL	4.61
Bilirubin (unconjugated)	50 mg/dL	0.471
	50 mg/dL	4.86
Hemoglobin	600 mg/dL	0.557
	1000 mg/dL	4.43
Lipemia (triglycerides)	1200 mg/dL	0.652
	2000 mg/dL	6.09
Rheumatoid factor	600 IU/mL	0.499
	600 IU/mL	4.56
Thyroid dysfunction impacts cystatin C levels [12].		
For further information on interfering substances refer to Young DS [13,14].		

Precision (Serum)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	0.554	0.896	4.33
CV [%]	2.15	1.06	0.505
Total precision CLSI (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	0.581	0.938	4.54
CV [%]	2.70	1.71	1.09

Method comparison (Serum; n=99)	
Test x	Competitor Cystatin C (BN ProSpec®)
Test y	DiaSys Cystatin C FS (BioMajesty® JCA-BM6010/C)
Slope	0.982
Intercept	–0.001 mg/L
Coefficient of correlation	0.998

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Reference Range [15,16,17]

	[mg/L]
Children	
4th and 5th day	1.22 – 1.68
< 1 month	1.37 – 1.89
1 – 12 months	0.73 – 1.17
> 12 months	0.60 – 0.84

Mean values +/- 1 SD (standard deviation) are listed

Adults	
19 – 49 years	0.53 – 0.92
≥ 50 years	0.58 – 1.02

Indication of 2 SD range

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

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