BioMajesty®

Cystatin C FS*

Order Information

Cat. No.	Kit size
1 7158 99 10 966	200 (R1: 2 x 100, R2: 2 x 100)

Intended Use

Diagnostic reagent for quantitative in vitro determination of cystatin C in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

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. The bottles are placed directly into the reagent rotor.

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.

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

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. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	0.2 mg/L
No prozone effect up to 30 mg/L.	
Onboard stability	12 weeks
Calibration stability	12 weeks

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

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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

	[mg/L]
Children [15]	
Preterm infants	0.8 – 2.3
Full-term infants	0.7 – 1.5
8 days - 16 years	0.5 – 1.3
Adults [16]	0.61 – 1.01

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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IVD CE

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* Fluid Stable

BioMajesty

Cystatin C FS

Chemistry code 10 715

Application for serum samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	90
R2e volume	0
R2 volume	30
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1.0
Sample vol (U)	1.0
Reagent 1 mix	strong
Reagent 2e mix	weak
Reagent 2 mix	strong
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	22
S-DET.P.r	23
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Sub-analy. Conditions	
Name	CYSC
Digits	3
M-wave L.	596
S-wave.L	****
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1.0	1.0
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

MULTI-STD Setting								
Formula	Spline	**Axis Conv**	No conv					
Blank	Blank-any value	**Points**	6					
	FV	**Reac. smp. vol.**	**Dil. method**	**Dil. smp. vol.**	**Diluent vol.**	**Diluent pos.**	**STD H**	**STD L**
BLK	#	1.0	No dil	0	0	0	9.999	-9.999
1	#	1.0	No dil	0	0	0	9.999	-9.999
2	#	1.0	No dil	0	0	0	9.999	-9.999
3	#	1.0	No dil	0	0	0	9.999	-9.999
4	#	1.0	No dil	0	0	0	9.999	-9.999
5	#	1.0	No dil	0	0	0	9.999	-9.999

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