

Cystatin C FS*

Order Information

Cat. No.

1 7158 99 10 921

Kit size

 400 (4 x 100)

Intended Use

Diagnostic reagent for quantitative in vitro determination of cystatin C in human serum or heparin plasma on automated DiaSys respons[®]910.

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. Do not freeze and protect from light.

Warnings and Precautions

- Components contained in Cystatin C FS are classified according to EC regulation 1272/2008 (CLP) as follows: Reagent 2: H412 Harmful to aquatic life with long lasting effects. P273 Avoid release to the environment. P501 Dispose of contents/container to hazardous or special waste collection point.
- Reagent 1 contains sodium azide (0.9 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 2 contains sodium azide (0.62 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- The reagents contain animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [10].
- 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.
- 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 7158 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 from 0.25 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	4 weeks
Calibration stability	1 week

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [mg/L]
Bilirubin (conjugated)	60 mg/dL	0.458
	60 mg/dL	4.63
Bilirubin (unconjugated)	60 mg/dL	0.460
	60 mg/dL	4.76
Hemoglobin	500 mg/dL	0.548
	1000 mg/dL	4.57
Lipemia (triglycerides)	1000 mg/dL	0.605
	1000 mg/dL	4.53
Rheumatoid factor	600 IU/mL	1.18
	600 IU/mL	4.41

Thyroid dysfunction impacts cystatin C levels [12].

For further information on interfering substances refer to Young DS [13,14].

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/L]	0.721	1.19	3.84
CV [%]	3.18	2.40	2.13
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/L]	0.760	1.19	4.05
CV [%]	6.04	3.21	2.50



Method comparison (n=105)	
Test x	DiaSys Cystatin C FS (Hitachi 917)
Test y	DiaSys Cystatin C FS (respons [®] 910)
Slope	0.943
Intercept	0.167 mg/L
Coefficient of correlation	0.999

* Fluid Stable

** according to CLSI document EP17-A, Vol. 24, No. 34

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

1. Erland J.E., Randers E., Kristensen J.H. Reference intervals for serum cystatin C and serum creatinine in adults. *Clin Chem Lab Med* 1998; 36(6):393-397.
2. Lamb E., Newman DJ, Price CP Kidney function tests. In: Burtis CA, Ashwood ER, Bruns DE, editors. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*. 4th edition St. Louis Missouri: Elsevier Saunders; 2006; p. 823-835.
3. Kyhse-Andersen, Schmidt C., Nordin G. et al. Serum cystatin C, determined by a rapid, automated particle-enhanced turbidimetric method, is a better marker than serum creatinine for glomerular filtration rate. *ClinChem* 1994; 40(10):1921-6.
4. Le Bricon T., Leblanc I et al. Evaluation of renal function in intensive care: plasma cystatin C vs. creatinine and derived glomerular filtration rates *Clin Chem Lab Med* 2005; 43(9):953-957.
5. Le Bricon T., Thervet E., Benlakehal M. et al. Changes in Plasma cystatin C after renal transplantation and acute rejection in adults. *Clin Chem* 1999; 45(12):2243-9
6. Ustundag Y., Samsar U. et al. Analysis of glomerular filtration rate, serum cystatin C levels, and resistive index values in cirrhosis patients. *Clin Chem Lab Med* 2007; 45(7):890-94.
7. Stabuc B., Vrhovec L. et al. Improved prediction of decreased creatinine clearance by serum cystatin C : Use in cancer patients before and during chemotherapy. *Clin Chem* 2000; 46(2):193-7.
8. Pucci L., Triscornia S., Lucchesi D. et al. Cystatin C and estimates of renal function: searching for a better measure of kidney function in diabetic patients. *Clin Chem* 2007; 53(3):480-8.
9. Strevens H, Wide-Svensson D, Grubb A. Serum cystatin C is a better marker for preeclampsia than serum creatinine or serum urate. *Scand J Clin Lab Invest* 2001; 61:575-80.
10. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. *ClinChemLabMed* 2007;45(9):1240-1243.
11. Guder WG, Zawta B. et al. *The Quality of Diagnostic Samples*. 1st ed. Darmstadt: GIT Verlag; 2001; p. 24-5.
12. Wiesli P., Schwegler B. et al. Serum cystatin C is sensitive to small changes in thyroid function. *Clinica Chimica Acta* 2003; 338: 87-90.
13. Young DS. *Effects of Drugs on Clinical Laboratory Tests*. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
14. Young DS. *Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products*, <https://clinf.wiley.com/aaccweb/aacc/>, accessed in August 2021. Published by AACC Press and John Wiley and Sons, Inc.
15. Soldin SJ, Brugnara C, Wong EC, American Association for Clinical Chemistry. *Pediatric Reference Intervals*. Sixth ed. Washington DC: AACC Press; 2007.
16. Erlandsen EJ, Randers E. Reference intervals for plasma cystatin C and plasma creatinine in adults using methods traceable to international calibrators and reference methods. *J Clin Lab Anal*. 2018; 32:e22433.

Cystatin C FS

Application for serum and heparin plasma 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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	CYSC
Shortcut:	
Reagent barcode reference:	720
Host reference:	720

Technic	
Type:	Fixed time kinetic
First reagent:[μ L]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[μ L]	60
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	508
Secondary wavelength:[nm]	
Polychromatic factor:	
1 st reading time [min:sec]	05:00
Last reading time [min:sec]	09:00
Reaction way:	Increasing
Linear Kinetics	
Substrate depletion: Absorbance li	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics	
Substrate depletion: Absorbance limit	
Endpoint	
Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [μ L]	0 (no hemolysis)
Cleaner	
Sample [μ L]	0
Technical limits	
Concentration technical limits-Lower	0.2000
Concentration technical limits-Upper	8.0000
SERUM	
Normal volume [μ L]	2.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	6
URINE	
Normal volume [μ L]	2.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [μ L]	2.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	6
CSF	
Normal volume [μ L]	2.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [μ L]	2.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	2.0
Above normal dilution (factor)	6

Results	
Decimals	2
Units	mg/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	19 - 49 y
SERUM	$\geq 0.53 \leq 0.92$
URINE	
PLASMA	$\geq 0.53 \leq 0.92$
CSF	
Whole blood	
Gender	
Age	50 -120 y
SERUM	$\geq 0.58 \leq 1.02$
URINE	
PLASMA	$\geq 0.58 \leq 1.02$
CSF	
Whole blood	

Contaminants	
Please refer to r910 Carryover Pair Table	

Calibrators details	
Calibrator list	Concentration
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
	Max delta abs.
Cal. 1	0.0050
Cal. 2	0.0050
Cal. 3	0.0100
Cal. 4	0.0150
Cal. 5	0.0150
Cal. 6	0.0150
Drift limit [%]	2.00

Calculations	
Model	Cubic Spline
Degree	

* Enter calibrator value