respons®920

Cystatin C FS*

Order Information

Cat. No.	Kit size
1 7158 99 10 921	Σ 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®920.

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 practices.
4. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
5. In very rare cases, samples of patients with gammopathy might give falsified results [10].
6. 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.
7. 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 from 0.1 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**	0.08 mg/L
No prozone effect up to 30 mg/L.	
Onboard stability	12 weeks
Calibration stability	2 weeks

Interfering substance	**Interferences ≤ 10% up to**
Bilirubin	60 mg/dL
Hemoglobin	1000 mg/dL
Lipemia (triglycerides)	1000 mg/dL
Rheumatoid factor	600 IU/mL
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]	0.70	0.95	3.08
CV [%]	2.53	2.26	1.88
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	0.91	1.12	3.44
CV [%]	3.71	3.08	3.53

Method comparison (n=100)	
Test x	Competitor Cystatin C (Nephelometer)
Test y	DiaSys Cystatin C FS (respons®920)
Slope	0.959
Intercept	–0.043 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

respons®920

Cystatin C FS

Application for Serum and Plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	CYSC				Auto Rerun	:	☐
Report Name	:	Cystatin C				Total Reagents	:	2
Unit	:	mg/L	Decimal Places	:	2	Reagent R1	:	CYSC R1
Wavelength-Primary	:	505	Secondary	:	0	Reagent R2	:	CYSC R2
Assay Type	:	2-Point	Curve Type	:	Cubic Spline			
M1 Start	:	19	M1 End	:	19	Consumables/Calibrators:		
M2 Start	:	31	M2 End	:	31	Blank/Level 0	:	0
Sample Replicates	:	1	Standard Replicates	:	3	Calibrator Level 1	:	**
Control Replicates	:	1	Control Interval	:	0	Calibrator Level 2	:	**
Reaction Direction	:	Increasing	React. Abs. Limit	:	*	Calibrator Level 3	:	**
Prozone Limit %	:	97	Prozone Check	:	Lower	Calibrator Level 4	:	**
Linearity Limit %	:	0	Delta Abs. / Min.	:	0.00	Calibrator Level 5	:	**
Technical Minimum	:	*	Technical Maximum	:	*			
Y = aX + b a=	:	1.00	b=	:	0.00			

* Technical limits are automatically defined by the software via the upper and lower calibrator level.
** Enter calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	CYSC		
Sample Type	:	Serum		

Sample Volumes

Normal	:	2.40 µL	Dilution Ratio	:	1 X
Increase	:	4.00 µL	Dilution Ratio	:	1 X
Decrease	:	2.00 µL	Dilution Ratio	:	1 X
Standard Volume	:	2.40 µL			

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	180 µL	R1 Stirrer Speed	:	Medium
RGT-2 Volume	:	60 µL	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	CYSC		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/L)	Upper Limit (mg/L)
Normal	:	0.53	0.92
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other