respons®910

# Cystatin C FS*

## Order Information

| Cat. No. | Kit size |
|---|---|
| 1 7158 99 10 921 | Σ 400 (4 x 100) |
| 1 7158 99 10 926 | Σ 200 (2 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. 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 from 0.25 up to 8 mg/L, depending on the concentration of the highest calibrator.<br>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 |

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

## 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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IVD CE

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* Fluid Stable

respons®910

# 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: | |

| Technic | |
|---|---|
| Type: | Fixed time kinetic |
| First reagent:[µL] | 180 |
| Blank reagent | Yes |
| Sensitive to light | |
| Second reagent:[µL] | 60 |
| Blank reagent | Yes |
| 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<br>Substrate depletion: Absorbance li | |
| Linearity: Maximum deviation [%] | |
| Fixed Time Kinetics<br>Substrate depletion: Absorbance limit | |
| Endpoint<br>Stability: Largest remaining slope | |
| Prozone Limit [%] | |

| Reagents | |
|---|---|
| Decimals | |
| Units | |

| Sample | |
|---|---|
| Diluent | DIL A (NaCl) |
| Hemolysis: | |
| Agent [µL] | 1 (no hemolysis) |
| Cleaner | |
| Sample [µL] | 0 |
| Technical limits | |
| Concentration technical limits-Lower | 0.20 |
| Concentration technical limits-Upper | 8.00 |
| SERUM | |
| Normal volume [µL] | 2 |
| Normal dilution (factor) | 1 |
| Below normal volume [µL] | 2 |
| Below normal dilution (factor) | 1 |
| Above normal volume [µL] | 2 |
| Above normal dilution (factor) | 6 |
| URIN | |
| Normal volume [µL] | 2 |
| Normal dilution (factor) | 1 |
| Below normal volume [µL] | 2 |
| Below normal dilution (factor) | 1 |
| Above normal volume [µL] | 2 |
| Above normal dilution (factor) | 6 |
| PLASMA | |
| Normal volume [µL] | 2 |
| Normal dilution (factor) | 1 |
| Below normal volume [µL] | 2 |
| Below normal dilution (factor) | 1 |
| Above normal volume [µL] | 2 |
| Above normal dilution (factor) | 6 |
| CSF | |
| Normal volume [µL] | 2 |
| Normal dilution (factor) | 1 |
| Below normal volume[ µL] | 2 |
| Below normal dilution (factor) | 1 |
| Above normal volume [µL] | 2 |
| Above normal dilution (factor) | 6 |
| Whole blood | |
| Normal volume [µL] | 2 |
| Normal dilution (factor) | 1 |
| Below normal volume[ µL] | 2 |
| Below normal dilution (factor) | 1 |
| Above normal volume [µL] | 2 |
| Above normal dilution (factor) | 6 |

| Results | |
|---|---|
| Decimals | 2 |
| Units | mg/L |
| Correlation factor-Offset | 0.000 |
| Correlation factor-Slope | 1.000 |

| Range | |
|---|---|
| Gender | All |
| Age | 19 - 49 y |
| SERUM | >=0.53 <=0.92 |
| URINE | |
| PLASMA | >=0.53 <=0.92 |
| CSF | |
| Whole blood | |
| Gender | |
| Age | 50 -120 y |
| SERUM | >=0.58 <=1.02 |
| URINE | |
| PLASMA | >=0.58 <=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 [%] | 2.0 |

| Calculations | |
|---|---|
| Model | Cubic Spline |
| Degree | Auto |

* Enter calibrator value