Cystatin C FS*

Reagent for quantitative in vitro determination of cystatin C in serum and plasma on photometric systems

Order Information
Cat. No. Kit size
1 7158 99 10 930 R1 4 x 12 mL + R2 2 x 8 mL
1 7150 99 10 059 R1 5 x 1 mL

TruCal Cystatin C:
Calibrator set with 5 different levels

Summary [1-9]
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, less dependent on factors such as sex, muscle mass and age. Cystatin C determination may be useful especially in children, elderly people, in diabetics, in patients with liver cirrhosis, in adult renal transplant recipients, in cancer patients and in pregnant suspected of preeclampsia.

Method
Particle enhanced immunoturbidimetric test

Principle
Determination of the 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
R2: Borate 7.5 mmol/L
Polyclonal antibodies (goat) against human Cystatin C bound to carboxylated polystyrene particles < 1%

Storage Instructions and Reagent Stability
The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided after opening. Do not freeze the reagents and keep them protected from light!

Warnings and Precautions
1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
2. The reagents contain animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
3. In very rare cases, samples of patients with gammopathy might give falsified results [16].
4. 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 patients’ medical history, clinical examinations and other findings.
5. For professional use only!

Waste Management
Please refer to local legal requirements.

Reagent Preparation
The reagents are ready to use.

Materials required but not provided
NaCl solution 9 g/L
General laboratory equipment

Specimen
Serum, heparin plasma
Stability [10]:
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 for Analyzers
Application sheets for automated systems are available on request.

Basic parameter for Hitachi 917

| Wavelength | 505 nm (monochromatic) |
| Temperature | 37°C |
| Measurement | 2-Point Test (Fixed Time Kinetics) |

| Sample/calibrator | 2 µL |
| Reagent 1 | 180 µL |
| Reagent 2 | 60 µL |
| Addition Reagent 2 | Cycle 16 (279 s) |
| Absorbance 1 | Cycle 20 (340 s) |
| Absorbance 2 | Cycle 30 (516 s) |
| Calibration | Spline function |

Note: For manual procedures the volumes of sample, calibrator and reagents have to be calculated appropriately and the timing has to be kept exactly.

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. Stability of calibration: 6 weeks

Calibrator and controls
DiaSys TruCal Cystatin C calibrator set is recommended for the calibration of automated photometric systems.
The assigned values of TruCal Cystatin C have been made traceable to the IFCC reference material ERM®DA471. For internal quality control the DiaSys TruLab Cystatin C controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
</tr>
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<tbody>
<tr>
<td>TruLab Cystatin C Level 1</td>
<td>5 9870 99 10 046 3 x 1 mL</td>
</tr>
<tr>
<td>TruLab Cystatin C Level 2</td>
<td>5 9880 99 10 046 3 x 1 mL</td>
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</table>

Performance characteristics

Measuring range
The test has been developed to determine Cystatin C concentrations within a measuring range from 0.1 – 8 mg/L, at least up to 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.
Prozone Limit
No prozone effect was observed up to a Cystatin C value of 30 mg/L.

Specificity/Interferences
Due to its antibodies DiaSys Cystatin C FS is a specific immunoassay for human Cystatin C. No significant interference was observed by conjugated and unconjugated bilirubin up to 60 mg/dL, hemoglobin up to 1000 mg/dL, lipemia up to 1000 mg/dL triglycerides, and RF up to 600 IU/mL. Thyroid dysfunction has an impact on cystatin C levels [11]. For further information on interfering substances refer to Young DS [15].

Sensitivity/Limit of Detection
The lower limit of detection is 0.08 mg/L.

Precision (at 37°C)

<table>
<thead>
<tr>
<th></th>
<th>Intra-assay</th>
<th>Inter-assay</th>
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<tbody>
<tr>
<td></td>
<td>n = 20</td>
<td>n = 20</td>
</tr>
<tr>
<td></td>
<td>Mean [mg/L]</td>
<td>Mean [mg/L]</td>
</tr>
<tr>
<td></td>
<td>SD [mg/L]</td>
<td>SD [mg/L]</td>
</tr>
<tr>
<td></td>
<td>CV [%]</td>
<td>CV [%]</td>
</tr>
<tr>
<td>Sample 1</td>
<td>0.62</td>
<td>0.87</td>
</tr>
<tr>
<td>Sample 2</td>
<td>0.89</td>
<td>1.15</td>
</tr>
<tr>
<td>Sample 3</td>
<td>3.19</td>
<td>3.32</td>
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Method comparison
A comparison of DiaSys Cystatin C FS (y) with a commercially available nephelometric test (x) using 100 samples gave the following results:

\[ y = 0.972 x + 0.049 \text{ mg/L}; r = 0.999 \]

Reference range [12,13,14] [mg/L]

<table>
<thead>
<tr>
<th></th>
<th>[mg/L]</th>
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<tbody>
<tr>
<td>Children:</td>
<td></td>
</tr>
<tr>
<td>4th and 5th day</td>
<td>1.22 - 1.68</td>
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<tr>
<td>&lt; 1 month</td>
<td>1.37 – 1.89</td>
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<tr>
<td>1 – 12 months</td>
<td>0.73 – 1.17</td>
</tr>
<tr>
<td>&gt; 12 months</td>
<td>0.60 – 0.84</td>
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Mean values +/- 1 SD are listed

<table>
<thead>
<tr>
<th></th>
<th>[mg/L]</th>
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<tbody>
<tr>
<td>Adults:</td>
<td></td>
</tr>
<tr>
<td>19 – 49 years</td>
<td>0.53 – 0.92</td>
</tr>
<tr>
<td>≥ 50 years</td>
<td>0.58 – 1.02</td>
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</table>

Indication of 2 SD range

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

Literature

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9  65558 Holzheim  Germany