Cystatin C FS*

Diagnostic reagent for quantitative in vitro determination of cystatin C in serum and plasma on DiaSys re- spons®920

Order Information
Cat. No. 1 7158 99 10 921
4 twin containers for 100 determinations each
Cat. No. 1 7158 99 10 926
2 twin containers for 100 determinations each

Method
Particle enhanced immunoturbidimetric test

Principle
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
Polyclonal Antibodies (goat) against human cystatin C bound to 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, protected from light and contamination is avoided. DiaSys respons containers provide protection from expiry, if stored at 2 – 8°C, protected from light. Do not freeze the reagents!

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. 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.
4. In very rare cases, samples of patients with gammapathy might give falsified results [16].
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
Please refer to local legal requirements.

Reagent Preparation
The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Specimen
Serum, heparin plasma
Stability [1]: 2 days at 20 – 25°C
1 week at 2 – 8°C
1 month at −20°C
Discard contaminated specimens. Freeze only once.

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

Performance Characteristics
Measuring range 0.1 - 8 mg/L cystatin C, at least up to 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 cystatin C
No prozone effect up to 30 mg/L cystatin C
On-board stability 12 weeks
Calibration stability 2 weeks

Interferences < 10% by
Bilirubin up to 60 mg/dL
Hemoglobin up to 1000 mg/dL
Lipemia (triglycerides) up to 1000 mg/dL
RF up to 800 IU/mL
Thyroid dysfunction has an impact on cystatin C levels [2].
For further information on interfering substances refer to Young DS [3].

Precision
Within run (n=20)

<table>
<thead>
<tr>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/L]</td>
<td>0.70</td>
<td>0.95</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>2.53</td>
<td>2.26</td>
</tr>
</tbody>
</table>

Between run (n=20)

<table>
<thead>
<tr>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/L]</td>
<td>0.91</td>
<td>1.12</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>3.71</td>
<td>3.08</td>
</tr>
</tbody>
</table>

Method comparison (n=100)

<table>
<thead>
<tr>
<th>Test x</th>
<th>Competitor Cystatin C (Nephelometer)</th>
<th>DiaSys Cystatin C FS (respons®920)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slope</td>
<td>0.999</td>
<td></td>
</tr>
<tr>
<td>Intercept</td>
<td>−0.043 mg/L</td>
<td></td>
</tr>
<tr>
<td>Coefficient of correlation</td>
<td>0.998</td>
<td></td>
</tr>
</tbody>
</table>

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Reference Range [4,5,6]

<table>
<thead>
<tr>
<th>[mg/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children:</td>
</tr>
<tr>
<td>4th and 5th day</td>
</tr>
<tr>
<td>&lt; 1 month</td>
</tr>
<tr>
<td>1 – 12 month(s)</td>
</tr>
<tr>
<td>&gt; 12 months</td>
</tr>
<tr>
<td>Mean values +/- 1 SD are listed</td>
</tr>
</tbody>
</table>

| 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 transferrable to its own patient population and determine own reference ranges if necessary.

* fluid stable
Literature


Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Straße 9 65558 Holzheim Germany
# Cystatin C FS

## Application for Serum and Plasma

### Test Details

- **Test:** CYSC
- **Sample Type:** Serum

### Test Volumes

- **Normal:** 2.40 µL
- **Increase:** 4.00 µL
- **Decrease:** 2.00 µL

### Reference Ranges

- **Category:** Male
- **Reference Range:** DEFAULT

## Sample Volumes

- **Normal:** 2.40 µL
- **Increase:** 4.00 µL
- **Decrease:** 2.00 µL

## Reagent Volumes and Stirrer Speed

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

### Y = aX + b

- a = 1.00
- b = 0.00

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