Cystatin C FS*

Diagnostic reagent for quantitative in vitro determination of cystatin C in serum and plasma on DiaSys re-spons®910

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
Polycional Antibodies (goat) against human cystatin C bound to to carboxylated polystyrene particles

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 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. In very rare cases, samples of patients with gammapathy 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 patient’s 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. The bottles are placed directly into the reagent rotator.

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 0.250 – 8.00 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).

<table>
<thead>
<tr>
<th>Interfering substance</th>
<th>Interferences &lt; 10%</th>
<th>CYSC [mg/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>up to 500 mg/dL</td>
<td>0.548</td>
</tr>
<tr>
<td>Bilirubin, conjugated</td>
<td>up to 60 mg/dL</td>
<td>4.58</td>
</tr>
<tr>
<td>Bilirubin, unconjugated</td>
<td>up to 60 mg/dL</td>
<td>4.63</td>
</tr>
<tr>
<td>Lipemia (triglycerides)</td>
<td>up to 100 mg/dL</td>
<td>4.65</td>
</tr>
<tr>
<td>Rheumatoid factor</td>
<td>up to 600 IU/mL</td>
<td>4.18</td>
</tr>
</tbody>
</table>

Thyroid dysfunction has an impact on cystatin C levels [2].

* For further information on interfering substances refer to Young DS [3].

Precision

<table>
<thead>
<tr>
<th>Within run (n=20)</th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/L]</td>
<td>0.721</td>
<td>1.19</td>
<td>3.84</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>3.18</td>
<td>2.40</td>
<td>2.13</td>
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</table>

<table>
<thead>
<tr>
<th>Between run (n=20)</th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/L]</td>
<td>1.790</td>
<td>1.19</td>
<td>4.05</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>0.04</td>
<td>3.21</td>
<td>2.50</td>
</tr>
</tbody>
</table>

Method comparison (n=105)

<table>
<thead>
<tr>
<th>Test x</th>
<th>DiaSys Cystatin C FS (Hitachi 917)</th>
<th>Test y</th>
<th>DiaSys Cystatin C FS (respons®910)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slope</td>
<td>0.943</td>
<td>Intercept</td>
<td>0.167 mg/L</td>
</tr>
<tr>
<td>Coefficient of correlation</td>
<td>0.999</td>
<td>0.999</td>
<td></td>
</tr>
</tbody>
</table>

** according to NCCLS document EP17-A, vol. 24, no. 34

Reference Range [4,5,6]

[| mg/L |
<table>
<thead>
<tr>
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</tbody>
</table>

Children:
4th and 5th day: 1.22 – 1.68
< 1 month: 1.37 – 1.89
1 – 12 month(s): 0.73 – 1.17
> 12 months: 0.60 – 0.84

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.

* fluid stable
Literature


Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany
### Identification

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

### 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

**CSF**
- Whole blood

**URINE**
- >=0.53 <=0.92

**PLASMA**
- Whole blood

### Contaminants

- Please refer to r910 Carryover Pair Table

### Calculators details

<table>
<thead>
<tr>
<th>Calibrator list</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cal. 1/Blank</td>
<td>0</td>
</tr>
<tr>
<td>Cal. 2</td>
<td></td>
</tr>
<tr>
<td>Cal. 3</td>
<td></td>
</tr>
<tr>
<td>Cal. 4</td>
<td></td>
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<tr>
<td>Cal. 5</td>
<td></td>
</tr>
<tr>
<td>Cal. 6</td>
<td></td>
</tr>
</tbody>
</table>

- **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

### Reagents

#### Decimals

- Units

#### Sample

- **Diluent**: DIL A (NaCl)
- **Agent [µL]**: 1 (no hemolysis)
- **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

#### URINE

- **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

### Technical limits

- **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

### Calculators

- **Model**: Cubic Spline
- **Degree**: Auto

* Enter calibrator value