**Complement C3c FS**

Diagnostic reagent for quantitative in vitro determination of complement component C3c in serum or plasma on DiaSys respons®’920

**Order Information**

Cat. No. 1 1802 99 10 921
4 twin containers for 100 determinations each

**Method**

Immunoturbidimetric test

**Principle**

Determination of the C3c concentration by photometric measurement of antigen-antibody-reaction of antibodies to human C3c with C3c present in the sample.

**Reagents**

**Components and Concentrations**

<table>
<thead>
<tr>
<th>Component</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1: TRIS</td>
<td>pH 7.5</td>
</tr>
<tr>
<td>NaCl</td>
<td>100 mmol/L</td>
</tr>
<tr>
<td>R2: TRIS</td>
<td>pH 8.0</td>
</tr>
<tr>
<td>NaCl</td>
<td>100 mmol/L</td>
</tr>
<tr>
<td>Anti-human C3 antibody (goat)</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>

**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**

2. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
3. Reagent 2 contains 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 reagents®’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 [6].
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**

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 or EDTA plasma

During storage of serum the C3 and C4 proteins slowly degrade into C3c resp. C4 fragments (fragmentation is inhibited by EDTA). These fragments still contain the reactive epitopes and may even display higher signals than the intact protein. Depending on the conditions of this aging process, fresh serum samples may show up to 30 % lower C3 values than samples stored at 2 – 8 °C for 8 days. The fragmentation of C4 is much slower than for C3 and only 15% lower values can be observed under similar storage conditions.

Discard contaminated specimens.

**Calibrators and Controls**

For calibration DiaSys TruCal Protein calibrator set or TruCal Protein high is recommended. The assigned values of the calibrators have been made traceable to the ERM®-DA470-k/IFCC Reference Material. For internal quality control a DiaSys TruLab Protein control should be assayed. Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

**Performance Characteristics**

Measuring range up to 500 mg/dL complement component C3c, 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 the rerun function.

- Limit of detection**: 1 mg/dL C3c
- No prozone effect up to 1000 mg/dL C3c
- On-board stability: 4 weeks
- Calibration stability: 4 weeks

**Interferences < 10% by**

- Bilirubin up to 60 mg/dL
- Hboglobin up to 1000 mg/dL
- Lipemia (triglycerides) up to 2000 mg/dL
- RP up to 1200 IU/mL
- IgA up to 6400 mg/dL
- IgM up to 4100 mg/dL
- IgG up to 8400 mg/dL

For further information on interfering substances refer to Young DS [2].

**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/dL]</td>
<td>59.4</td>
<td>132</td>
<td>199</td>
</tr>
<tr>
<td>Coefficient of variance [%]</td>
<td>0.71</td>
<td>0.99</td>
<td>0.82</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Between run (n=20)</th>
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<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/dL]</td>
<td>59.7</td>
<td>132</td>
<td>199</td>
</tr>
<tr>
<td>Coefficient of variance [%]</td>
<td>1.69</td>
<td>1.96</td>
<td>1.90</td>
</tr>
</tbody>
</table>

**Method comparison (n=105)**

<table>
<thead>
<tr>
<th>Test x</th>
<th>DiaSys C3c FS (Hitachi 917)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test y</td>
<td>DiaSys C3c FS (response 920)</td>
</tr>
<tr>
<td>Slope</td>
<td>1.024</td>
</tr>
<tr>
<td>Intercept</td>
<td>–2.78 mg/dL</td>
</tr>
<tr>
<td>Coefficient of correlation</td>
<td>0.996</td>
</tr>
</tbody>
</table>

**Reference Range**

90 – 180 mg/dL (0.9 – 1.8 g/L)

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

**Literature**


**Manufacturer**

DiaSys Diagnostic Systems GmbH
Alte Strasse 9
65585 Holzheim
Germany

* fluid stable
**Complement C3c FS**

Application for serum and plasma

<table>
<thead>
<tr>
<th>Test Details</th>
<th>Test Volumes</th>
<th>Reference Ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>C3c</td>
<td>Auto Rerun</td>
</tr>
<tr>
<td>Report Name</td>
<td>Complement C3c</td>
<td>Online Calibration</td>
</tr>
<tr>
<td>Unit</td>
<td>mg/dL</td>
<td>Decimal Places</td>
</tr>
<tr>
<td>Wavelength-Primary</td>
<td>340</td>
<td>Secondary</td>
</tr>
<tr>
<td>Assay Type</td>
<td>2-Point</td>
<td>Curve Type</td>
</tr>
<tr>
<td>M1 Start</td>
<td>16</td>
<td>M1 End</td>
</tr>
<tr>
<td>M2 Start</td>
<td>33</td>
<td>M2 End</td>
</tr>
</tbody>
</table>

**Consumables/Calibrators:**
- **Sample Replicates**: 1
- **Control Replicates**: 1
- **Prozone Direction**: Increasing
- **Prozone Limit %**: 97
- **Linearity Limit %**: 0
- **Technical Minimum**: *
- **Technical Maximum**: *
- **Technical Y = aX + b**
  - a: 1.0000
  - b: 0.0000

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

**Enter calibrator value.**

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<tbody>
<tr>
<td>Test</td>
<td>C3c</td>
<td>Sample Type</td>
</tr>
<tr>
<td>Sample Type</td>
<td>Serum</td>
<td></td>
</tr>
</tbody>
</table>

**Sample Volumes**
- **Normal**: 2.60 µL
- **Increase**: 10.00 µL
- **Decrease**: 2.00 µL
- **Standard Volume**: 2.60 µL

**Reagent Volumes and Stirrer Speed**
- **RGT-1 Volume**: 180 µL
- **R1 Stirrer Speed**: Medium
- **RGT-2 Volume**: 36 µL
- **R2 Stirrer Speed**: High

**Reference Range**
- **Normal**: 90.00 - 180.00
- **Panic**: 0 - 90.00

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**Test Details**
- **Test**: C3c
- **Sample Type**: Serum

**Reference Ranges**
- **Category**: Male
- **Sample Types**: Serum, CSF, Plasma, Whole Blood, Other

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*Enter calibrator value.*