CRP FS*

Diagnostic reagent for quantitative in vitro determination of C-reactive protein (CRP) in serum or plasma on photometric systems

Order Information
Cat. No. Kit size
1 7002 99 10 021 R1 5 x 25 mL + R2 1 x 25 mL
1 7002 99 10 023 R1 1 x 1000 mL + R2 1 x 200 mL
1 7002 99 10 704 R1 8 x 50 mL + R2 8 x 10 mL
1 7002 99 10 917 R1 8 x 60 mL + R2 8 x 12 mL
1 7002 99 10 930 R1 4 x 20 mL + R2 2 x 8 mL
1 7002 99 10 935 R1 2 x 20 mL + R2 1 x 8 mL
1 7002 99 10 941 R1 4 x 60 mL + R2 4 x 12 mL
1 7002 99 90 314 R1 10 x 20 mL + R2 2 x 25 mL
1 7000 99 10 039 5 x 2 mL TruCal CRP:
Calibrator set with 5 different levels

Summary [1-4]
C-reactive protein (CRP) is the best known among the acute-phase proteins, a group of proteins whose concentration increases in blood as a response to inflammatory disorders (acute-phase response). CRP is normally present in low concentration in blood of healthy individuals (< 5 mg/L). It is elevated up to 500 mg/L in acute inflammatory processes associated with bacterial infections, post-operative conditions or tissue damage already after 6 hours reaching a peak at 48 hours. The measurement of CRP represents a useful laboratory test for detection of acute infection as well as for monitoring inflammatory processes also in acute rheumatic and gastrointestinal diseases. CRP testing shows various advantages in comparison to the erythrocyte sedimentation rate (ESR) and the leucocyte count. In fact, it is more sensitive, the increase occurs earlier and its levels return to the reference range more rapidly after healing.

Method
Immunoturbidimetric test

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

Reagents
Components and Concentrations
R1: TRIS pH 7.5 100 mmol/L
R2: TRIS pH 8.0 100 mmol/L
Anti-human CRP antibodies (goat) <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. Do not freeze the reagents and protect them from light!

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. In very rare cases, samples of patients with gammopathy might give falsified results [9].
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.

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

Specimen
Serum, heparin plasma or EDTA plasma

Stability [5]: 15 days at 20 – 25°C
2 months at 4 – 8°C
3 years at −20°C

Only freeze once! Discard contaminated specimens.

Assay Procedure for Analyzers
Application sheets for automated systems are available on request.

Wavelength 340 nm, Hg 334 nm
Optical path 1 cm
Temperature 37°C
Measurement Against reagent blank

Sample or calibrator
Blank 15 µL
Dist. Water 15 µL
Reagent 1 250 µL
Mixture, incubate for 5 min. at 37 °C and read absorbance (A1), then add:
Reagent 2 50 µL
Mixture, incubate for 5 min. at 37°C and read absorbance (A2),

\[ \Delta A = (A2 - A1) \text{ sample or calibrator} \]

Calculation
The CRP concentration of unknown samples is derived from a calibration curve using an appropriate mathematical model such as logit/log. 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: 4 weeks

Calibrators and Controls
For the calibration of automated photometric systems, DiaSys TruCal CRP calibrator set is recommended. The assigned values of TruCal CRP have been made traceable to the ERM®-DA474/IFCC reference material. For internal quality control, DiaSys TruLab CRP or TruLab Protein control 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>
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</thead>
<tbody>
<tr>
<td>TruLab CRP Level 1</td>
<td>5 9600 99 10 045 3 x 2 mL</td>
</tr>
<tr>
<td>TruLab CRP Level 2</td>
<td>5 9610 99 10 045 3 x 2 mL</td>
</tr>
<tr>
<td>TruLab Protein Level 1</td>
<td>5 9500 99 10 046 3 x 1 mL</td>
</tr>
<tr>
<td>TruLab Protein Level 2</td>
<td>5 9510 99 10 046 3 x 1 mL</td>
</tr>
</tbody>
</table>

* fluid stable
Performance Characteristics

Measuring Range
The measuring range is from 2 mg/L up to the concentration of the highest calibrator, at least up to 250 mg/L. When values exceed these ranges, 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 CRP concentration of 2000 mg/L.

Specificity/Interferences
Due to its antibodies, DiaSys CRP FS is a specific immunoassay for human CRP. No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 500 mg/dL and lipemia up to 2000 mg/dL triglycerides as well as by anticoagulants in usual concentrations. For further information on interfering substances refer to Young DS.[8]

Sensitivity/Limit of Detection
The lower limit of detection is 2 mg/L.

Precision (n = 20)

<table>
<thead>
<tr>
<th></th>
<th>Mean [mg/L]</th>
<th>SD [mg/L]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-assay precision</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample 1</td>
<td>6.6</td>
<td>0.3</td>
<td>4.7</td>
</tr>
<tr>
<td>Sample 2</td>
<td>20.4</td>
<td>0.6</td>
<td>3.0</td>
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<tr>
<td>Sample 3</td>
<td>88.5</td>
<td>3.1</td>
<td>3.5</td>
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<tr>
<td>Inter-assay precision</td>
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<td></td>
</tr>
<tr>
<td>(daily calibration)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Sample 1</td>
<td>7.3</td>
<td>0.4</td>
<td>5.9</td>
</tr>
<tr>
<td>Sample 2</td>
<td>22.1</td>
<td>0.6</td>
<td>2.6</td>
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<tr>
<td>Sample 3</td>
<td>95.0</td>
<td>1.2</td>
<td>1.3</td>
</tr>
<tr>
<td>Inter-assay precision</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>(single calibration)</td>
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<tr>
<td>Sample 1</td>
<td>7.2</td>
<td>0.4</td>
<td>5.7</td>
</tr>
<tr>
<td>Sample 2</td>
<td>22.2</td>
<td>0.4</td>
<td>1.8</td>
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<tr>
<td>Sample 3</td>
<td>97.8</td>
<td>2.4</td>
<td>2.5</td>
</tr>
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</table>

Method Comparison
A comparison of DiaSys CRP FS (y) to a commercially available test (x) using 65 samples gave following results:
y = 0.99 x +0.00 mg/L; r = 0.997

Reference Range [6,7]

- Adults: < 5 mg/L
- Newborn up to 3 weeks: < 4.1 mg/L
- Infants and children: < 2.8 mg/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 65558 Holzheim Germany