CRP IS*

Diagnostic reagent for quantitative in vitro determination of C-reactive protein (CRP) in whole blood and plasma on InnovaStar®

Order Information
Cat. No. 2 7069 99 10 760 100 determinations + cleaner 2 7069 99 10 761 50 determinations + cleaner 970 100 InnovaStar® (instrument) 970 113 10 x 100 Sample Cups InnovaStar® 10/500 920 709 10 x 100 "open end" capillaries 10 µL (heparinized) 970 115 300 mL system solution InnovaStar®

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 the detection of acute infection as well as for monitoring inflammatory processes; among others 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
Particle enhanced immunoturbidimetric test

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

Reagents
Components and Concentrations
R1: Glycine <1.5%
R2: Glycine <1.5%
Antibodies (rabbit) against human CRP bound to polystyrene particles 0.2%

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. 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 the detection of acute infection as well as for monitoring inflammatory processes; among others 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.

Warnings and Precautions
1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucus membranes.
2. In very rare cases, samples of patients with gammopathy might give falsified results. [8]
3. 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.
4. For professional use only!

Waste Management
Please refer to local legal requirements.

Reagent Preparation
The reagent is ready to use.
Bring reagent to room temperature. Make sure that the reagent is at the bottom of the cartridge.

Specimen
Capillary blood (taken with heparinized capillary), heparin plasma or EDTA plasma (venous)
Discard contaminated specimens.

Stability in plasma [5]:
15 days at 20 - 25°C
2 months at 4 - 8°C
3 years at -20°C
Freeze only once!

Sample preparation
For sample preparation, sample cups InnovaStar® 10/500 (magenta cap) and open-end capillaries (10 µL heparinized) are required. Take the patient sample with open-end capillary as described in the user manual. Put the filled capillary in the sample cup. Mix the sample thoroughly by inversion. The measurement should be started immediately but not later than 20 minutes after sample preparation. Controls should be assayed immediately after sample preparation.

Assay Procedure
Application is read by the ParamCard (see user manual InnovaStar®)
For every measurement of CRP, a cup with cleaner (orange cup) has to be placed in last position of the slider (one cup of cleaner is sufficient for 10 measurements). Unit (mg/dL or mg/L) can be chosen when reading the ParamCard for the first time.

Hematocrit-corrected CRP concentration
Hematocrit correction is automatically performed for each CRP measurement. The correction is carried out by a simultaneously determined individual hematocrit value. If the individual hematocrit value is >60%, the alarm message “HctH” is displayed on the instrument and no result is reported.

Capillary blood CRP values lower than 5 mg/L are reported semi-quantitatively using the ranges 0 - 2 and 2 - 5 mg/L. Plasma CRP values lower than 2 mg/L are reported semi-quantitatively using the range 0 - 2 mg/L. Higher concentrations are reported quantitatively.

Calibration
The calibration is stored on the ParamCard which is included in the reagent kit and is read after the receipt of the reagent (see user manual InnovaStar®). The calibration stability is 9 months. Fourteen days before the recalibration date, the instrument points to recalibration. This requires that a lot-specific code for the registration of a recalibration curve is entered into the instrument. For recalibration codes please refer to http://www.diasys-diagnostics.com/service-area/recalibration-of-innovastar®.

The procedure of entering the code is described in the user manual for InnovaStar®. The successful entry of the recalibration curve has to be verified by the measurement of controls. The assigned values for calibration have been made traceable to the ERM®/IFCC reference material.

Controls
For internal quality control DiaSys TruLab CRP controls should be assayed. Controls must be prepared the same way as patient samples and assayed immediately after preparation. 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>
</thead>
<tbody>
<tr>
<td>TruLab CRP level 1</td>
<td>5 9600 99 10 045</td>
</tr>
<tr>
<td>TruLab CRP level 2</td>
<td>5 9610 99 10 045</td>
</tr>
</tbody>
</table>

* InnovaStar®
Performance Characteristics

Measuring range
Depending on the hematocrit correction, the measuring range for capillary blood is given from 5 mg/L up to 400 mg/L, for plasma from 2 mg/L up to 160 mg/L.

Prozone Limit
No prozone effect was observed up to a CRP concentration of 1800 mg/L.

Specificity/Interferences
No interference has been observed up to levels of 800 IU/mL RF, 60 mg/dL bilirubin, 60 mg/dL ditaurobilirubin and 1800 mg/dL triglycerides. For further information on interfering substances refer to Young DS [6].

Sensitivity/Limit of Detection
The lower limit of detection for capillary blood is 5 mg/L.
The lower limit of detection for plasma is 2 mg/L.

Precision (n=20) in whole blood

<table>
<thead>
<tr>
<th>Total precision n=20</th>
<th>Mean [mg/L]</th>
<th>SD [mg/L]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>4.33</td>
<td>0.134</td>
<td>3.1</td>
</tr>
<tr>
<td>Sample 2</td>
<td>10.6</td>
<td>0.218</td>
<td>2.1</td>
</tr>
<tr>
<td>Sample 3</td>
<td>41.5</td>
<td>0.693</td>
<td>1.7</td>
</tr>
</tbody>
</table>

Method comparison
A comparison of DiaSys CRP IS (y) to a commercially available test (x) using 90 samples, lead to the following results:

\[ y = 0.961 \times 0.025 \text{ mg/L}. \]

Coefficient of correlation: \( r = 0.996 \).

Reference Range [7]

Adults

\(< 5 \text{ mg/L}\)

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