InnovaStar®

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 + 10 x 1800 µL Cleaner (Article number 970112) + 1 x ParamCard (Article number 970116)
2 7069 99 10 761	50 determinations + 10 x 1800 µL Cleaner (Article number 970112) + 1 x ParamCard (Article number 970116)
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 leukocyte 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. Do not freeze reagents and protect them from light! Damaged or opened reagent cartridges must not be used!

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. 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

EDTA/heparin whole blood or EDTA/heparin plasma
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 cups) 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.

	Cat. No.	Kit size
TruLab CRP level 1	5 9600 99 10 045	3 x 2 mL
TruLab CRP level 2	5 9610 99 10 045	3 x 2 mL

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 in whole blood

Within run precision according to CLSI	Mean [mg/L]	SD [mg/L]	CV [%]
Sample 1	4.32	0.144	3.33
Sample 2	10.4	0.388	3.71
Sample 3	41.6	1.01	2.43

Total precision according to CLSI	Mean [mg/L]	SD [mg/L]	CV [%]
Sample 1	4.32	0.215	4.98
Sample 2	10.4	0.418	4.01
Sample 3	41.6	1.23	2.97

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 x – 0.025 mg/L. Coefficient of correlation: r = 0.996.

Reference Range [7]

Adults < 5 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

1. Thompson D, Milford-Ward A, Whicher JT. The value of acute phase protein measurements in clinical practice. Ann Clin Biochem 1992;29:123-31.
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3. Hansson LO, Lindquist L. C-reactive protein: its role in the diagnosis and follow-up of infectious diseases. Curr Opin Infect Diseases 1997; 10:196-201.
4. Sipe JD. Acute-phase proteins in osteoarthritis. Semin Arthritis Rheum 1995;25: 75-86.
5. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 24-5.
6. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
7. Dati F, Schumann G, Thomas L, Aguzzi F, Baudner S, Bienvenu J et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470). Eur J Clin Chem Clin Biochem 1996;34:517-20.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

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Manufacturer

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