CRP IS*

Order Information

Cat. No.	Kit size
2 7069 99 10 760	Σ 100 + 10 x 1800 µL Cleaner (Cat. No. 970112) + 1 x ParamCard (Cat. No. 970116)
2 7069 99 10 761	Σ 50 + 10 x 1800 µL Cleaner (Cat. No. 970112) + 1 x ParamCard (Cat. No. 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 (Sodium-heparinized)
970 115	300 mL System solution InnovaStar®

Intended Use

Diagnostic reagent for quantitative in vitro determination of C-reactive protein (CRP) in human sodium heparinized capillary whole blood on automated InnovaStar®. It is intended for the detection of acute infection as well as for monitoring inflammatory processes. For professional use only.

Summary

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; 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. [1-4]

Method

Particle enhanced immunoturbidimetric test

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%
	Anti-human CRP antibodies (rabbit) bound to polystyrene particles	< 0.2%

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C. Do not freeze. Do not use damaged or open reagent cartridges.

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 material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [5].
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
6. Please refer to the safety data sheets (SDS) 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.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

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

Materials Required

General laboratory equipment

Specimen

Sodium heparinized capillary whole blood

Discard contaminated specimens.

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

Calibration

The calibration is stored on the ParamCard 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 a recalibration curve is entered into the instrument. For recalibration codes, refer to https://www.diasys-diagnostics.com/service-area/support/recalibration-of-innovastarr. 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®-DA474/IFCC reference material.

Controls

Use DiaSys TruLab CRP Level 1 and Level 2 for internal quality control on every measuring day. An external quality control is recommended. Controls must be prepared the same way as patient samples and assayed immediately after preparation. Quality control must be performed after entering recalibration codes. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each user should establish corrective action in case of deviation 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

Data evaluated on InnovaStar®

Measuring range up to 400 mg/L, depending on the concentration of the highest calibrator.	
Limit of detection	5 mg/L
No prozone effect up to 1800 mg/L.	

Interference by	**Interferences ≤ 13.5% up to**
Bilirubin (conjugated)	60 mg/dL
Bilirubin (unconjugated)	60 mg/dL
Lipemia (triglycerides)	1800 mg/dL
Rheumatoid factor	800 IU/mL
For further information on interfering substances, refer to the literature [6,7,8].	

Precision			
Within run according to CLSI	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	4.32	10.4	41.6
CV [%]	3.33	3.71	2.43
Total precision CLSI (n=80)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	4.32	10.4	41.6
CV [%]	4.98	4.01	2.97

Method comparison (n=90)	
Test x	Competitor CRP (Hitachi 917)
Test y	DiaSys CRP IS (InnovaStar®)
Slope	0.961
Intercept	–0.025 mg/L
Coefficient of correlation	0.996

Reference Range [9]

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.
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5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed. 2007;45:1240–1243.
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.
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9. Dati F, 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.

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IVD CE

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