

## CRP IS\*

### Order Information

| Cat. No.         | Kit size   |
|------------------|--|
| 2 7069 99 10 760 | ∇ $\Sigma$ 100 + 10 x 1800 $\mu$ L Cleaner<br>(Cat. No. 970112)<br>+ 1 x ParamCard (Cat. No. 970116) |
| 2 7069 99 10 761 | ∇ $\Sigma$ 50 + 10 x 1800 $\mu$ L Cleaner<br>(Cat. No. 970112)<br>+ 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 $\mu$ L<br>(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 an acute-phase protein, a group of proteins whose concentration increases in blood as a response to inflammatory disorders (acute-phase response). It is a pentamer consisting of five identical polypeptide chains and is synthesized in the liver. Measurement of CRP is used to screen and monitor the course of the acute phase response (e.g. in fever and/or postoperative period), in infections (e.g. to monitor antibiotic therapy) and to diagnose inflammatory processes (e.g. chronic inflammatory disease such as rheumatic, gastrointestinal, respiratory, etc.). Further CRP measurement can aid in the differential diagnosis of gastrointestinal complaints as well as the management of rheumatic diseases and atherosclerosis. Additionally, CRP can be used to support the differentiation between viral and bacterial infections. CRP is elevated after 6 hours reaching a peak at 48 hours, and declines with a half-life of 19 hours [1]. This allows for early detection of inflammatory processes. In many cases, the increase in CRP precedes clinical symptoms. The level of CRP correlates well with inflammatory activity in acute inflammation and infection. Therefore, CRP can be used to differentiate between low-grade, mild, moderate and high-grade inflammation [2].

### 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

|  |        |
|--|--------|
| <b>R1:</b> Glycine   | < 1.5% |
| <b>R2:</b> Glycine   | < 1.5% |
| Anti-human CRP antibodies (rabbit)<br>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

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- The reagents contain material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [3].

- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- 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.
- 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  $\mu$ L/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. All target values of the controls are traceable to DiaSys reagent/calibrator system. 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 | Analyte concentration [mg/L] |
|---------------------------------|-----------------------------|------------------------------|
| <b>Bilirubin</b> (conjugated)   | 60 mg/dL                    | 2.55                         |
|                                 | 60 mg/dL                    | 38.5                         |
| <b>Bilirubin</b> (unconjugated) | 60 mg/dL                    | 6.62                         |
|                                 | 60 mg/dL                    | 45.5                         |
| <b>Lipemia</b> (triglycerides)  | 1800 mg/dL                  | 3.39                         |
|                                 | 1800 mg/dL                  | 38.3                         |
| <b>Rheumatoid factor</b>        | 800 IU/mL                   | 6.22                         |
|                                 | 800 IU/mL                   | 31.4                         |

For further information on interfering substances, refer to the literature [4-6].

| Precision                |          |          |          |
|--------------------------|----------|----------|----------|
| Repeatability (n=80)     | Sample 1 | Sample 2 | Sample 3 |
| Mean [mg/L]              | 4.32     | 10.4     | 41.6     |
| CV [%]                   | 3.33     | 3.71     | 2.43     |
| Within-laboratory (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 [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. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2024 [cited 2024 Jul 09]. <https://www.clinical-laboratory-diagnostics.com>
2. Vigushin DM, et al. Metabolic and scintigraphic studies of radioiodinated human C-reactive protein in health and disease. *J Clin Invest.* 1993;91:1351-1357
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. *ClinChemLabMed.* 2007;45:1240-1243.
4. 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.
5. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, <https://clinfx.wiley.com/aaccweb/aacc/>, accessed in May 2023. Published by AACC Press and John Wiley and Sons, Inc..
6. Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. *Ann Clin Biochem.* 2001;38:376-85.
7. 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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DiaSys Diagnostic Systems GmbH  
Alte Strasse 9 65558 Holzheim  
Germany  
[www.diasys-diagnostics.com](http://www.diasys-diagnostics.com)

\* InnovaStar®