respons®910

DiaSys Diagnostic Systems

# CRP U-hs*

**Diagnostic reagent for quantitative in vitro determination of C-reactive protein (CRP) in serum or plasma on DiaSys respons®910**

## Order Information

**Cat. No. 1 7045 99 10 920**
4 Twincontainer for 100 tests each

## Method

Particle enhanced immunoturbidimetric test for high sensitive range. The high sensitive application is recommended for samples with concentrations lower than 20 mg/L and where high precision and extremely good sensitivity is required.

## Principle

Fixed time 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:** HEPES pH 7.2 10 mmol/L
**R2:** Borate buffer 4.6 mmol/L
Polyclonal (goat) and monoclonal (mouse) anti-human CRP antibodies bound to carboxylated polystyrene particles

### 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, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

### 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 [9].
3. Heterophile antibodies in patient samples may cause falsified results.
4. 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.
5. For professional use only!

### Waste Management

Please refer to local legal requirements.

### Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor. Avoid formation of foam.

## Specimen

Serum, heparin plasma or EDTA plasma
Stability [1]:

| | | |
|---|---|---|
| 15 days | at | 20 – 2 °C |
| 2 months | at | 4 – 8°C |
| 3 years | at | –20°C |

Discard contaminated specimens. Only freeze once.

## Calibrators and Controls

For calibration, the DiaSys TruCal CRP hs calibrator set is recommended. The assigned values of TruCal CRP hs have been made traceable to the IFCC reference material ERM®-DA474. For internal quality control, DiaSys TruLab CRP hs controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

| | Cat. No. | Kit size | | |
|---|---|---|---|---|
| TruCal CRP hs 5 Levels | 1 7080 99 10 059 | 5 | x | 1 mL |
| TruLab CRP hs Level 1 | 5 9730 99 10 046 | 3 | x | 1 mL |
| TruLab CRP hs Level 2 | 5 9740 99 10 046 | 3 | x | 1 mL |

## Performance Characteristics
## High sensitive application

| | |
|---|---|
| Measuring range from 0.6 to 20 mg/L CRP (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function). | |
| Limit of detection** | 0.2 mg/L CRP |
| No prozone effect up to 700 mg/L CRP | |
| On-board stability | 2 weeks |
| Calibration stability | 2 weeks |

| Interfering substance | Interferences < 10% | CRP [mg/L] |
|---|---|---|
| **Hemoglobin** | up to 250 mg/dL | 2.43 |
| | up to 300 mg/dL | 14.5 |
| **Bilirubin, conjugated** | up to 60 mg/dL | 1.32 |
| | up to 50 mg/dL | 13.8 |
| **Bilirubin, unconjugated** | up to 60 mg/dL | 1.38 |
| | up to 45 mg/dL | 13.8 |
| **Lipemia** | up to 1400 mg/dL | 2.22 |
| (triglycerides conc. Sero) | up to 2000 mg/dL | 4.89 |
| For further information on interfering substances refer to Young DS [2]. | | |

| **Precision** | | | |
|---|---|---|---|
| **Within run (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [mg/L] | 1.02 | 1.75 | 4.48 |
| Coefficient of variation [%] | 4.68 | 3.57 | 3.68 |
| **Between run (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [mg/L] | 0.84 | 4.28 | 8.44 |
| Coefficient of variation [%] | 9.37 | 4.32 | 6.34 |

| **Method comparison (n=77)** | |
|---|---|
| Test x | DiaSys CRP U-hs (Hitachi 917) |
| Test y | DiaSys CRP U-hs (respons®910) |
| Slope | 1.06 |
| Intercept | 0.024 mg/L |
| Coefficient of correlation | 0.998 |

** according to NCCLS document EP17-A, vol. 24, no. 34

## Reference Range [3,4]

| | |
|---|---|
| Adults | < 5 mg/L |
| Newborns 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


1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 24 -5.
2. 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.
3. 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.
4. Schlebusch H, Liappis N, Klein G. High sensitive CRP and creatinine: reference intervals from infancy to childhood. Poster presented at AACC/CSCC; July/August 2001, Chicago, Illinois.
5. Thompson D, Milford-Ward A, Whicher JT. The value of acute phase protein measurements in clinical practice. Ann Clin Biochem 1992; 29: 123-31.
6. Gabay C, Kushner I. Acute-phase proteins and other systemic responses to inflammation. N Engl J Med 1999; 340: 448-54.
7. 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.
8. Sipe JD. Acute-phase proteins in osteoarthritis. Semin Arthritis Rheum 1995; 25: 75-86.
9. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.


## Manufacturer

IVD CE

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respons®910

DiaSys Diagnostic Systems

# CRP U-hs (sensitive appl.)

## Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel

| Identification | |
|---|---|
| This method is usable for analysis: | Yes |
| Twin reaction: | No |
| Name: | CRP hs |
| Shortcut: | |
| Reagent barcode reference: | 722 |
| Host reference: | |

| Technic | |
|---|---|
| Type: | Fixed time kinetic |
| First reagent:[µL] | 100 |
| Blanc correction | No |
| Second reagent:[µL] | 100 |
| Blanc correction | No |
| Main wavelength:[nm] | 508 |
| Secondary wavelength:[nm] | |
| Polychromatic factor: | |
| 1 st reading time [min:sec] | 05:00 |
| Last reading time [min:sec] | 10:00 |
| Reaction way: | Increasing |
| Linear Kinetics<br>Substrate depletion: Absorbance limit | |
| Linearity: Maximum deviation [%] | |
| Fixed Time Kinetics<br>Substrate depletion: Absorbance limit | |
| Endpoint<br>Stability: Largest remaining slope | |
| Prozone Limit [%] | |

| Sample | |
|---|---|
| Diluent | DIL A (NaCl) |
| Hemolysis: | |
| Agent [µL] | 0 (no hemolysis) |
| Sample [µL] | 0 |
| Concentration technical limits-Lower | 0.3 |
| Concentration technical limits-Upper | 20 |
| SERUM | |
| Normal volume [µL] | 15 |
| Normal dilution (factor) | 1 |
| Below normal volume [µL] | 20 |
| Below normal dilution (factor) | 1 |
| Above normal volume [µL] | 5 |
| Above normal dilution (factor) | 1 |
| URIN | |
| Normal volume [µL] | 15 |
| Normal dilution (factor) | 1 |
| Below normal volume [µL] | 20 |
| Below normal dilution (factor) | 1 |
| Above normal volume [µL] | 5 |
| Above normal dilution (factor) | 1 |
| PLASMA | |
| Normal volume [µL] | 15 |
| Normal dilution (factor) | 1 |
| Below normal volume [µL] | 20 |
| Below normal dilution (factor) | 1 |
| Above normal volume [µL] | 5 |
| Above normal dilution (factor) | 1 |
| CSF | |
| Normal volume [µL] | 15 |
| Normal dilution (factor) | 1 |
| Below normal volume[ µL] | 20 |
| Below normal dilution (factor) | 1 |
| Above normal volume [µL] | 5 |
| Above normal dilution (factor) | 1 |

| Results | |
|---|---|
| Decimals | 2 |
| Units | mg/L |
| Correlation factor-Offset | 0.000 |
| Correlation factor-Slope | 1.000 |

| Range | |
|---|---|
| Gender | All |
| Age | Adults |
| SERUM | >= <=5 |
| URINE | |
| PLASMA | >= <=5 |
| CSF | |
| Gender | |
| Age | |
| SERUM | |
| URINE | |
| PLASMA | |
| CSF | |

| Contaminants | |
|---|---|
| Contaminant 1 | Please refer to r910 Carryover Pair Table |
| Wash with | |
| Cycle | |
| Volume [µL] | |
| Contaminant 2 | |
| Wash with | |
| Cycle | |
| Volume [µL] | |
| Contaminant 3 | |
| Wash with | |
| Cycle | |
| Volume [µL] | |
| Contaminant 4 | |
| Wash with | |
| Cycle | |
| Volume [µL] | |

| Calibrators details | |
|---|---|
| **Calibrator list** | **Concentration** |
| Cal. 1/Blank | 0 |
| Cal. 2 | * |
| Cal. 3 | * |
| Cal. 4 | * |
| Cal. 5 | * |
| Cal. 6 | * |

| | Max delta abs. |
|---|---|
| Cal. 1 | 0.0100 |
| Cal. 2 | 0.0100 |
| Cal. 3 | 0.0100 |
| Cal. 4 | 0.0100 |
| Cal. 5 | 0.0150 |
| Cal. 6 | 0.0150 |
| Drift limit [%] | 2.0 |

| Calculations | |
|---|---|
| Model | Cubic Spline |
| Degree | Auto |

* Enter calibrator value