respons®910

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

DiaSys Diagnostic Systems GmbH
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respons®910

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:	707
Host reference:	722

Technic	
Type:	Fixed time kinetic
First reagent:[µL]	100
Blank reagent	No
Sensitive to light	
Second reagent:[µL]	100
Blank reagent	No
Sensitive to light	
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 Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	0.3000
Concentration technical limits-Upper	20.0000
SERUM	
Normal volume [µL]	15.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	5.0
Above normal dilution (factor)	1
URINE	
Normal volume [µL]	15.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	5.0
Above normal dilution (factor)	1
PLASMA	
Normal volume [µL]	15.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	5.0
Above normal dilution (factor)	1
CSF	
Normal volume [µL]	15.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	5.0
Above normal dilution (factor)	1
Whole blood	
Normal volume [µL]	15.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	5.0
Above normal dilution (factor)	1

Results	
Decimals	2
Units	mg/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	>= <=5.00
URINE	
PLASMA	>= <=5.00
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

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	

* Enter calibrator value