respons®920

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®920

Order information

Cat. No. 1 7045 99 10 920
4 twin containers for 100 determinations each

Method

Particle enhanced immunoturbidimetric test with two applications. 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 (measuring range of hs application: 0.05 mg/L – 20 mg/L). The universal application is characterized by a wide measuring range (2.5 – 350 mg/L) and low sample volume.

Principle

Determination of the CRP concentration 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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
3. In very rare cases, samples of patients with gammopathy might give falsified results [9].
4. Heterophile antibodies in patient samples may cause falsified results.
5. 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.
6. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. Do not shake and avoid foaming. The bottles are placed directly into the reagent rotor.

Specimen

Serum, heparin plasma or EDTA plasma

Stability [1]:			
	15 days	at	20 – 25°C
	2 months	at	4 – 8°C
	3 years	at	–20°C

Only freeze once! Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal CRP U calibrator set (universal range) or DiaSys TruCal CRP hs calibrator set (high-sensitive range) are recommended for calibration. The assigned values of the calibrators have been made traceable to the IFCC reference material ERM®-DA474/IFCC. For internal quality control, DiaSys TruLab CRP or TruLab Protein (universal range) or TruLab CRP hs (high sensitive range) controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal CRP U (5 Level)	1 7040 99 10 059	5 x 1 mL
TruCal CRP hs (5 Level)	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
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
TruLab Protein Level 1	5 9500 99 10 046	3 x 1 mL
TruLab Protein Level 2	5 9510 99 10 046	3 x 1 mL

Performance Characteristics Universal Application

Measuring range from 2.5 to 350 mg/L CRP, at least up to the concentration of the highest calibrator (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use the rerun function).	
Limit of detection**	0.8 mg/L CRP
No prozone effect up to 1000 mg/L CRP	
On-board stability	8 weeks
Calibration stability	6 weeks

Interfering substance	Interferences < 10%	CRP [mg/L]
Hemoglobin	up to 700 mg/dL	4.15
	up to 1200 mg/dL	40.7
Bilirubin, conjugated	up to 70 mg/dL	4.15
	up to 70 mg/dL	41.6
Bilirubin, unconjugated	up to 60 mg/dL	4.21
	up to 60 mg/dL	42.6
Lipemia (triglycerides)	up to 2100 mg/dL	3.96
	up to 2100 mg/dL	41.0
Rheumatoidfactor	up to 600 IU/mL	4.41
For further information on interfering substances refer to Young DS [8].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	5.68	11.7	68.0
Coefficient of variation [%]	2.13	1.51	1.99
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	4.74	11.8	68.6
Coefficient of variation [%]	3.72	2.30	2.91

Method comparison (n=153)	
Test x	DiaSys CRP U-hs (Hitachi 917)
Test y	DiaSys CRP U-hs (respons®920)
Slope	1.01
Intercept	0.123 mg/L
Coefficient of correlation	0.994

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

Performance Characteristics high sensitive Application

Measuring range from 0.05 to 20 mg/L CRP, at least up to the concentration of the highest calibrator (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use the rerun function).	
Limit of detection**	0.05 mg/L CRP
No prozone effect up to 800 mg/L CRP	
On-board stability	7 weeks
Calibration stability	3 weeks

Interfering substance	Interferences < 10%	CRP [mg/L]
Lipemia (triglycerides)	up to 1450 mg/dL	1.29
For further information on interfering substances refer to Young DS [8].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	0.38	2.20	18.0
Coefficient of variation [%]	3.35	0.97	1.44
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	0.74	1.80	11.5
Coefficient of variation [%]	2.46	1.68	2.80

Method comparison (n=111)	
Test x	DiaSys CRP U-hs (Hitachi 911)
Test y	DiaSys CRP U-hs (respons®920)
Slope	1.02
Intercept	0.042 mg/L
Coefficient of correlation	0.999

** lowest measurable activity which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

* U-hs: Universal and high-sensitive

Reference Range [2,3]

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

IVD CE

Hersteller

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respons®920

DiaSys Diagnostic Systems

CRP U-hs

Universal application for serum und plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	CRPU				Auto Rerun		☐
Report Name	:	C-Reactive Protein Universal				Online Calibration		☐
Unit	:	mg/L	Decimal Places	:	2	Cuvette Wash		☐
Wavelength-Primary	:	505	Secondary	:	0	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	4P Logit Log	Reagent R1	:	CRP U-hs R1
M1 Start	:	19	M1 End	:	19	Reagent R2	:	CRP U-hs R2
M2 Start	:	31	M2 End	:	31	**Consumables/Calibrators:**		
Sample Replicates	:	1	Standard Replicates	:	3	Blank /Level 0	:	0
Control Replicates	:	1	Control Interval	:	0	Calibrator 1	:	**
Reaction Direction	:	Increasing	React. Abs. Limit	:	*	Calibrator 2	:	**
Prozone Limit %	:	97	Prozone Check	:	Lower	Calibrator 3	:	**
Linearity Limit %	:	0	Delta Abs. / Min.	:	0.00	Calibrator 4	:	**
Technical Minimum	:	*	Technical Maximum	:	*	Calibrator 5	:	**
Y = aX + b a=		1.00	b=	:	0.00			

*Technical limits are automatically defined by the software via the upper and lower calibrator level.
** Enter calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	CRPU		
Sample Type	:	Serum		

Sample Volumes

Normal	:	2.0	µL	Dilution Ratio	:	1 X
Increase		4.0	µL	Dilution Ratio	:	1 X
Decrease		2.0	µL	Dilution Ratio	:	6 X
Standard Volume	:	2.0	µL			

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	120	µL	R1 Stirrer Speed	: Medium
RGT-2 Volume	:	120	µL	R2 Stirrer Speed	: Medium

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	CRPU		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/L)	Upper Limit (mg/L)
Normal	:	0.00	5.00
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

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CRP U-hs

hs application for Serum and Plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	CRPhs				Auto Rerun	:	☐
Report Name	:	CRP high sensitive				Online Calibration		☐
Unit	:	mg/L	Decimal Places	:	3	Cuvette Wash		☐
Wavelength-Primary	:	505	Secondary	:	0	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	Cubic Spline	Reagent R1		CRP U-hs R1 :
M1 Start	:	19	M1 End	:	19	Reagent R2	:	CRP U-hs R2
M2 Start	:	33	M2 End	:	33	**Consumables/Calibrators:**		
Sample Replicates	:	1	Standard Replicates	:	3	Blank /Level 0		0
Control Replicates	:	1	Control Interval	:	0	Calibrator 1		**
Reaction Direction	:	Increasing	React. Abs. Limit	:	*	Calibrator 2		**
Prozone Limit %	:	97	Prozone Check	:	Lower	Calibrator 3		**
Linearity Limit %	:	0	Delta Abs. / Min.	:	0.00	Calibrator 4		**
Technical Minimum	:	*	Technical Maximum	:	*	Calibrator 5		**
Y = aX + b a=	:	1.00	b=	:	0.00			

*Technical limits are automatically defined by the software via the upper and lower calibrator level.
** Enter calibrator value.

Test Details			Test Volumes	Reference Ranges
Test	:	CRPhs		
Sample Type	:	Serum		

Sample Volumes

Normal	:	10.00 µL	Dilution Ratio	:	1	X
Increase	:	20.00 µL	Dilution Ratio	:	1	X
Decrease	:	5.00 µL	Dilution Ratio	:	1	X
Standard Volume	:	10.00 µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	90 µL	R1 Stirrer Speed	:	Medium
RGT-2 Volume	:	90 µL	R2 Stirrer Speed	:	Medium

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	CRPhs		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mg/L)	Upper Limit (mg/L)
Normal	:	0.00	5.00
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other