

CRP FS*

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 7002 99 10 920

4 twin containers for 200 determinations each

Method

Immunoturbidimetric test

Principle

Determination of the concentration of CRP by photometric measurement of antigen-antibody reaction between antibodies against human CRP and CRP present in the sample.

Reagents

Components and Concentrations

R1:	TRIS	pH 7.5	100 mmol/L
R2:	TRIS	pH 8.0	100 mmol/L
	Anti-human CRP antibodies (goat)		< 1%

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 reagents!

Warnings and Precautions

1. Reagent 1: Warning. H319 Causes serious eye irritation. P280 Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention.
2. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Reagent 2: contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
4. 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.
5. In very rare cases, samples of patients with gammopathy might give falsified results [9].
6. 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.
7. 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.

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. Freeze only once.

Calibrators and Controls

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

	Cat. No.	Kit size
TruCal CRP Five Levels	1 7000 99 10 039	5 x 2 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

Measuring range up to 250 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 rerun function).	
Limit of detection**	1 mg/L CRP
No prozone effect up to 2000 mg/L CRP	
On-board stability	4 weeks
Calibration stability	4 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Hemoglobin up to 400 mg/dL
Bilirubin up to 60 mg/dL
Lipemia (triglycerides) up to 800 mg/dL
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]	9.83	23.8	59.6
Coefficient of variation [%]	3.88	1.30	0.98
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/L]	8.97	24.5	60.0
Coefficient of variation [%]	4.43	2.94	1.90

Method comparison (n=114)	
Test x	DiaSys CRP FS (Hitachi 917)
Test y	DiaSys CRP FS (respons [®] 920)
Slope	1.01
Intercept	-1.81 mg/L
Coefficient of correlation	0.999

** lowest measurable concentration which can be distinguished from zero mean + 1.645 SD (n=60) of an analyte free specimen

Reference Range [3,4]



Adults	<5 mg/L
Newborn 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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CRP FS

Application for serum and plasma

Test Details		Test Volumes		Reference Ranges	
Test	: CRP			Auto Rerun	<input type="checkbox"/>
Report Name	: C - Reactive Protein			Online Calibration	<input type="checkbox"/>
Unit	: mg/L	Decimal Places	: 2	Cuvette Wash	<input type="checkbox"/>
Wavelength-Primary	: 340	Secondary	: 700	Total Reagents	: 2
Assay Type	: 2-Point	Curve Type	: Cubic spline	Reagent R1	: CRP R1
M1 Start	: 15	M1 End	: 15	Reagent R2	: CRP 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.	: 0.0000	Calibrator 4	: **
Technical Minimum	: *	Technical Maximum	: *	Calibrator 5	: **
Y = aX + b	a= : 1.0000	b= : 0.0000		Calibrator 6	: **

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	: CRP				
Sample Type	: Serum				
Sample Volumes				Sample Types	
Normal	: 11.00 μ L	Dilution Ratio	: 1 X	<input checked="" type="checkbox"/> Serum	
Increase	: 20.00 μ L	Dilution Ratio	: 1 X	<input type="checkbox"/> Urine	
Decrease	: 5.00 μ L	Dilution Ratio	: 1 X	<input type="checkbox"/> CSF	
Standard Volume	: 11.00 μ L			<input checked="" type="checkbox"/> Plasma	
				<input type="checkbox"/> Whole Blood	
				<input type="checkbox"/> Other	
Reagent Volumes and Stirrer Speed					
RGT-1 Volume	: 180 μ L	R1 Stirrer Speed	: High		
RGT-2 Volume	: 36 μ L	R2 Stirrer Speed	: High		

Test Details		Test Volumes		Reference Ranges	
Test	: CRP				
Sample Type	: Serum				
Reference Range	: DEFAULT				
Category	: Male				
Reference Range				Sample Types	
	Lower Limit		Upper Limit	<input checked="" type="checkbox"/> Serum	
	(mg/L)		(mg/L)	<input type="checkbox"/> Urine	
Normal	: 0.00		: 5.00	<input type="checkbox"/> CSF	
Panic	: 0.00		: 0.00	<input checked="" type="checkbox"/> Plasma	
				<input type="checkbox"/> Whole Blood	
				<input type="checkbox"/> Other	