respons®910

CRP FS*

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 7002 99 10 920
4 twin containers for 200 tests 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. In very rare cases, samples of patients with gammopathy might give falsified results [9].
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. 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

For the calibration the DiaSys TruCal CRP calibrator set is recommended. The assigned values of TruCal CRP have been made traceable to the ERM®-DA474/IFCC reference material. 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**	2 mg/L CRP
No prozone effect up to 2000 mg/L CRP	
On-board stability	4 weeks
Calibration stability	1 week

Interfering substance	**Interferences < 10%**	**CRP [mg/L]**
Ascorbate	up to 30 mg/dL	31.2
Hemoglobin	up to 50 mg/dL	13.1
	up to 200 mg/dL	40.5
Bilirubin, conjugated	up to 10 mg/dL	9.5
	up to 40 mg/dL	37.8
Bilirubin, unconjugated	up to 20 mg/dL	11.4
	up to 60 mg/dL	39.2
Lipemia (triglycerides)	up to 1000 mg/dL	9.5
	up to 900 mg/dL	35.6
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]	11.1	22.7	59.3
Coefficient of variation [%]	2.91	2.89	1.39
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	10.8	20.5	61.8
Coefficient of variation [%]	5.16	3.13	2.14

Method comparison (n=105)	
Test x	DiaSys CRP FS (Hitachi 917)
Test y	DiaSys CRP FS (respons®910)
Slope	0.972
Intercept	–0.039 mg/L
Coefficient of correlation	0.999

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

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

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

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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
Shortcut:	
Reagent barcode reference:	706
Host reference:	706

Technic	
Type:	End point
First reagent:[µL]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	36
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	340
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
1 st reading time [min:sec]	(04:24)
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	2.0000
Concentration technical limits-Upper	250.0000
SERUM	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
URINE	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
PLASMA	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
CSF	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
Whole blood	
Normal volume [µL]	11.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
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	0.0300
Drift limit [%]	2.00

Calculations	
Model	Cubic Spline
Degree	

* Enter calibrator value