BioMajesty

CRP FS*

Diagnostic reagent for quantitative in vitro determination of C-reactive protein (CRP) in serum or plasma on BioMajesty JCA-BM6010/C

Order Information

Cat. No.	Tests		
1 7002 99 10 963	R1	4 x	570 tests
	R2	3 x	760 tests
1 7002 99 10 962	R1	6 x	380 tests
	R2	6 x	380 tests

Method

Immunoturbidimetric test

Principle

Determination of CRP concentration 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. Do not freeze the 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 [8].
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 examination 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 trays.

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

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

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

	Cat. No.	Kit size
TruCal CRP	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**	0.1 mg/L CRP
No prozone effect up to 2000 mg/L CRP	
On-board stability	6 weeks
Calibration stability	6 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Conjugated bilirubin up to 60 mg/dL
Unconjugated bilirubin up to 60 mg/dL
Hemoglobin up to 500 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
For further information on interfering substances refer to Young DS [7].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	7.30	22.3	43.9
Coefficient of variation [%]	1.10	0.85	2.66
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	7.45	22.5	43.8
Coefficient of variation [%]	1.94	1.31	1.44

Method comparison (n=100)	
Test x	Competitor CRP test
Test y	DiaSys CRP FS
Slope	1.02
Intercept	0.156 mg/L
Coefficient of correlation	1.00

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

Reference Range [2]

Adults < 5 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. Thompson D, Milford-Ward A, Whicher JT. The value of acute phase protein measurements in clinical practice. Ann Clin Biochem 1992; 29: 123-31.
4. Gabay C, Kushner I. Acute-phase proteins and other systemic responses to inflammation. N Engl J Med 1999; 340: 448-54.
5. 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.
6. Sipe JD. Acute-phase proteins in osteoarthritis. Semin Arthritis Rheum 1995; 25: 75-86.
7. 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.
8. 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
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BioMajesty

CRP FS

Chemistry code 10 700

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.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	16
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	4.8
Sample vol (U)	4.8
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Sub-analy. Conditions	
Name	CRP
Digits	2
M-wave L.	340
S-wave.L	694
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	4.8	4.8
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

MULTI-STD Setting			
Formula	Logit Log 3	**Axis Conv**	No conv
Blank	Blank is 0	**Points**	6

	FV	Reac. smp. vol.	Dil. method	Dil. smp. vol.	Diluent vol.	Diluent pos.	STD H	STD L
BLK	#	4.8	No dil	0	0	0	9.999	-9.999
1	#	4.8	No dil	0	0	0	9.999	-9.999
2	#	4.8	No dil	0	0	0	9.999	-9.999
3	#	4.8	No dil	0	0	0	9.999	-9.999
4	#	4.8	No dil	0	0	0	9.999	-9.999
5	#	4.8	No dil	0	0	0	9.999	-9.999

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