

CRP FS*


Order Information


Cat. No.

1 7002 99 10 963

1 7002 99 10 962

Kit size

 2280 (R1: 4 x 570, R2: 3 x 760)

 2280 (R1: 6 x 380, R2: 6 x 380)

Intended Use

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

Summary

C-reactive protein (CRP) is an acute-phase protein, a group of proteins whose concentration increases in blood as a response to inflammatory disorders (acute-phase response). It is a pentamer consisting of five identical polypeptide chains and is synthesized in the liver. Measurement of CRP is used to screen and monitor the course of the acute phase response (e.g. in fever and/or postoperative period), in infections (e.g. to monitor antibiotic therapy) and to diagnose inflammatory processes (e.g. chronic inflammatory disease such as rheumatic, gastrointestinal, respiratory, etc.). Further CRP measurement can aid in the differential diagnosis of gastrointestinal complaints as well as the management of rheumatic diseases and atherosclerosis. Additionally, CRP can be used to support the differentiation between viral and bacterial infections. CRP is elevated after 6 hours reaching a peak at 48 hours, and declines with a half-life of 19 hours [1]. This allows for early detection of inflammatory processes. In many cases, the increase in CRP precedes clinical symptoms. The level of CRP correlates well with inflammatory activity in acute inflammation and infection. Therefore, CRP can be used to differentiate between low-grade, mild, moderate and high-grade inflammation [2].

Method

Immunoturbidimetric test

Determination of CRP concentration by photometric measurement of antigen antibody reaction of antibodies to human CRP with 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 and Stability


Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

Warnings and Precautions

- Components contained in CRP FS are classified according to EC regulation 1272//2008 (CLP) as follows:



 Reagent 1: Warning. H319 Causes serious eye irritation. P280 Wear protective gloves/protective clothing/eye 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.

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 2 contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [3].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.

- Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
- Please refer to the safety data sheets (SDS) 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.
- For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [4]:

11 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 calibrator is recommended for calibration. Calibrator values have been made traceable to the reference material ERM®-DA474/IFCC. DiaSys TruCal CRP high may be used alternatively for calibration. Use DiaSys TruLab CRP Level 1 and Level 2 or TruLab Protein Level and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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
TruCal CRP high	1 7000 99 10 037	3 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 from 2 mg/L up to 300 mg/L, depending on the concentration of the highest calibrator. Linearity is given within ± 10%.	
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
Limit of quantitation**	2 mg/L
No prozone effect up to 2000 mg/L.	
Onboard stability	15 weeks
Calibration stability	13 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [mg/L]
Bilirubin (conjugated)	60 mg/dL	10.5
	60 mg/dL	41.0
Bilirubin (unconjugated)	60 mg/dL	10.5
	60 mg/dL	43.1
Hemolysis	900 mg/dL	10.7
	1200 mg/dL	38.7
Lipemia (triglycerides)	1400 mg/dL	8.94
	2000 mg/dL	37.9
Rheumatoid factor	150 IU/mL	9.54
	360 IU/mL	38.4

For further information on interfering substances, refer to the literature [5-7].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/L]	7.30	18.8	151
CV [%]	1.10	0.631	2.63
Within-laboratory (n=80)	Sample 1	Sample 2	Sample 3
Mean [mg/L]	5.71	19.3	149
CV [%]	4.47	2.26	3.26

Method comparison (n=167)	
Test x	Competitor CRP (cobas c 501)
Test y	DiaSys CRP FS (BioMajesty® JCA-BM6010/C)
Slope	1.10
Intercept	0.217 mg/L
Coefficient of correlation	0.991

** according to CLSI document EP17-A2, Vol. 32, No. 8

Reference Range [8,9]

Adults	< 5.0 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. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2024 [cited 2024 Jul 09]. <https://www.clinical-laboratory-diagnostics.com>
2. Vigushin DM, et al. Metabolic and scintigraphic studies of radioiodinated human C-reactive protein in health and disease. *J Clin Invest.* 1993;91:1351–1357
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. *ClinChemLabMed.* 2007;45:1240–1243.
4. W.G. Guder, F. da Fonseca-Wollheim, W. Heil, et al. Quality of Diagnostic Samples. German Society for Clinical Chemistry and Laboratory Medicine. 3rd completely revised edition 2010.
5. 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.
6. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products [Internet]. AACC Press and John Wiley and Sons, Inc; 2021 [cited 2022 Mar]. Available from: <https://clinfx.wiley.com/aaccweb/aacc/>
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8. Dati F, 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.
9. Schlebusch H, et al. High sensitive CRP and creatinine: reference intervals from infancy to childhood. Poster presented at AACC/CSCC; July/August 2001, Chicago, Illinois.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim
Germany
www.diasys-diagnostics.com

* Fluid Stable

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.l	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.l.	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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