CRP FS*

Order Information

Cat. No.	Kit size		
1 7002 99 10 021	R1 5 x 25 mL	+	R2 1 x 25 mL
1 7002 99 10 023	R1 1 x 1000 mL	+	R2 1 x 200 mL
1 7002 99 10 704	R1 8 x 50 mL	+	R2 8 x 10 mL
1 7002 99 10 917	R1 8 x 60 mL	+	R2 8 x 12 mL
1 7002 99 10 930	R1 4 x 20 mL	+	R2 2 x 8 mL
1 7002 99 10 935	R1 2 x 20 mL	+	R2 1 x 8 mL

Kits for use in conjunction with DiaSys CE applications.

Intended Use

Diagnostic reagent for quantitative in vitro determination of C-reactive protein (CRP) in human serum or heparin plasma on automated photometric systems.

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

1. 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.

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 material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
4. In very rare cases, samples of patients with gammopathy might give falsified results [3].
5. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
6. 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.
7. 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.
8. 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.

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.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	340/694 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	4.8 µL
Reagent 1	80 µL
Reagent 2	16 µL
Addition reagent 2	Cycle 19 (286 s)
Absorbance 1	Cycle 17/18 (231 s/244 s)
Absorbance 2	Cycle 41/42 (586 s/600 s)
Calibration	Logit Log 3

Calculation

The CRP concentration of unknown samples is derived from a calibration curve using an appropriate mathematical model such as logit/log. The calibration curve is obtained with five calibrators at different levels and NaCl solution (9 g/L) for determination of the zero value.

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

Data evaluated on BioMajesty® JCA-BM6010/C

Measuring range from 2 mg/L up to 300 mg/L, depending on the concentration of the highest calibrator. Linearity is given within ± 10%. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.	
Limit of detection**	2 mg/L
Limit of quantitation**	2 mg/L
No prozone effect up to 2000 mg/L.	

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

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IVD CE

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