CRP FS*

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

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
1 7002 99 10 941	R1	4 x	60 mL	+	R2	4 x	12 mL
1 7002 99 90 314	R1	10 x	20 mL	+	R2	2 x	25 mL
1 7000 99 10 039		5 x	2 mL	TruCal CRP: Calibrator set with 5 different levels			

Summary [1-4]

C-reactive protein (CRP) is the best known among the acute-phase proteins, a group of proteins whose concentration increases in blood as a response to inflammatory disorders (acute-phase response). CRP is normally present in low concentration in blood of healthy individuals (< 5 mg/L). It is elevated up to 500 mg/L in acute inflammatory processes associated with bacterial infections, post-operative conditions or tissue damage already after 6 hours reaching a peak at 48 hours. The measurement of CRP represents a useful laboratory test for detection of acute infection as well as for monitoring inflammatory processes also in acute rheumatic and gastrointestinal diseases. CRP testing shows various advantages in comparison to the erythrocyte sedimentation rate (ESR) and the leukocyte count. In fact, it is more sensitive, the increase occurs earlier and its levels return to the reference range more rapidly after healing.

Method

Immunoturbidimetric test

Principle

Determination of CRP concentration by photometric measurement of the 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 Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents and protect them from light!

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.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin plasma or EDTA plasma

Stability [5]:	15 days	at	20 – 25°C
	2 months	at	4 – 8°C
	3 years	at	–20°C

Only freeze once! Discard contaminated specimens.

Assay Procedure for Analyzers

Application sheets for automated systems are available on request.

Wavelength	340 nm, Hg 334 nm
Optical path	1 cm
Temperature	37°C
Measurement	Against reagent blank

	Blank	Sample or calibrator
Sample or calibrator	-	15 µL
Dist. Water	15 µL	-
Reagent 1	250 µL	250 µL
Mix, incubate for 5 min. at 37 °C and read absorbance (A1), then add:		
Reagent 2	50 µL	50 µL
Mix, incubate for 5 min. at 37°C and read absorbance (A2).		

$\Delta A = (A2–A1)$ sample or calibrator

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.
Stability of calibration: 4 weeks

Calibrators and Controls

For the calibration of automated photometric systems, 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, 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
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

* fluid stable

Performance Characteristics

Measuring Range

The measuring range is from 2 mg/L up to the concentration of the highest calibrator, at least up to 250 mg/L.
When values exceed these ranges, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Prozone Limit

No prozone effect was observed up to a CRP concentration of 2000 mg/L.

Specificity/Interferences

Due to its antibodies, DiaSys CRP FS is a specific immunoassay for human CRP. No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 500 mg/dL and lipemia up to 2000 mg/dL triglycerides as well as by anticoagulants in usual concentrations. For further information on interfering substances refer to Young DS [8].

Sensitivity/Limit of Detection

The lower limit of detection is 2 mg/L.

Precision (n = 20)

Intra-assay precision	Mean [mg/L]	SD [mg/L]	CV [%]
Sample 1	6.6	0.3	4.7
Sample 2	20.4	0.6	3.0
Sample 3	88.5	3.1	3.5

Inter-assay precision (daily calibration)	Mean [mg/L]	SD [mg/L]	CV [%]
Sample 1	7.3	0.4	5.9
Sample 2	22.1	0.6	2.6
Sample 3	95.0	1.2	1.3

Inter-assay precision (single calibration)	Mean [mg/L]	SD [mg/L]	CV [%]
Sample 1	7.2	0.4	5.7
Sample 2	22.2	0.4	1.8
Sample 3	97.8	2.4	2.5

Method Comparison

A comparison of DiaSys CRP FS (y) to a commercially available test (x) using 65 samples gave following results:
y = 0.99 x +0.00 mg/L; r = 0.997

Reference Range [6,7]

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

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5. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 24-5.
6. 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: p. 517-20.
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Manufacturer

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