

Quantitative determination of C-Reactive Protein (CRP)

IVD For in vitro-diagnostic use only

2°C - 8°C
Store at 2-8°C.

INTRODUCTION

CRP is an acute-phase protein present in normal serum, which increases significantly after most forms of tissue injuries, bacterial and virus infections, inflammation and malignant neoplasia. During tissue necrosis and inflammation resulting from microbial infections, the CRP concentration can rise up to 300 mg/L in 12-24 hours.

PRINCIPLE

The Latex particles coated with anti-CRP are agglutinated when they react with samples that contain C-Reactive Protein (CRP). The latex particles agglutination is proportional to the concentration of the CRP in the sample and can be measured by turbidimetry.

REAGENTS

Diluent (R1)	Tris buffer 20 mmol/L, pH 8.2. Sodium azide 0.95 g/L. Ready to use.
Latex (R2)	Latex particles coated with goat anti-human CRP, pH 7.3. Sodium azide 0.95 g/L. Ready to use. Mix gently the vial by inversion before use (See Note 4).
CRP-CAL	Human serum. CRP concentration is stated on the label vial and it is traceable to the Reference Material anti-streptolysin BCR 470 (IRMM). Ready to use.

ADDITIONAL EQUIPMENT

- Thermostatic bath at 37°C.
- Spectrophotometer or photometer thermostatable at 37°C a 540 ± 20 nm filters.

PREPARATION

Working reagent: Swirl the latex vial gently before use. Mix latex and diluent in a 1:5 ratio (i.e. 2ml latex reagent (R2) + 8 ml diluent (R1)) prior to use.

STORAGE AND STABILITY

1. The reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not use the reagents after the expiration date.
2. Working reagent is stable during 20 days at 2-8 °C. Shake gently the vial before use.
3. Reagent deterioration: presence of particles and turbidity.

PRECAUTIONS

- The reagents contain sodium azide 0.95 g/l. Avoid any contact with skin or mucous.
- The reagents from human donors have been given negative results to anti-HIV 1\2, HBsAg and anti-HCV. Handle cautiously is recommended.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.

SAMPLES

Fresh serum. Stable 7 days at 2-8°C or 3 months a -20°C. The samples with presence of fibrin should be centrifuged before testing. Hemolyzed or contaminated samples are not suitable for testing.

PROCEDURE

Preliminary Procedure

Pre-warm the working reagent and photometer (cuvette holder) to 37°C.

Analytical Procedure

1. Using distilled water zero the instrument at 540 nm.
2. Pipette into a Cuvette:

Working Reagent (mL)	1.0
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Calibrator or sample (µL)	5.0
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3. Mix well and record the absorbance immediately (A1) and after 2 minutes (A2) of the sample addition.

CALCULATION

$$\frac{(A_2 - A_1) \text{ sample}}{(A_2 - A_1) \text{ Calibrator}} \times \text{calibrator concentration} = \text{mg/L CRP}$$

QUALITY CONTROL

Control Sera are recommended to monitor the performance of manual and automated assay procedures.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

Adults: up to 5 mg/L.

Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTIC

• Linearity limit:

Up to 150 mg/L, under the described assay conditions. Samples with higher concentrations, should be diluted 1/5 in NaCl 9 g/L and retested again.

• Detection limit:

Values less than 1 mg/L give non-reproducible results.

• Analytical Sensitivity:

2.9 mA/mg CRP/L.

• Prozone effect:

Up to 250 mg/L

• Precision:

	Intra-assay (n=10)			Inter-assay (n=10)		
Mean (IU/mL)	8.0	19.7	71.8	8.0	19.7	71.8
CV %	6.7	3.7	2.6	5.3	5.6	4.3

• Accuracy:

Results obtained with these reagents did not show systematic differences when compared with

commercial reagents of similar characteristics. Details of comparison are available on request.

• Interferences

Bilirubin (40 mg/dL), hemoglobin (12 g/L), Lipemia (10 g/L) and rheumatoid factors (800 IU/mL) do not interfere. Other substances may interfere.

NOTES

1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meets the performance characteristic of the method .it is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.
2. The linearity limit depends on the sample/reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
3. Clinical diagnosis should not be made findings of a single test result, but should integrate both clinical and laboratory data.
4. For automatic instruments, avoid the presence of bubbles in the reagents that may interfere with the assay results.

REFERENCE

1. Hassoun LO, Lindquist L. Current opinin in infectious diseases. 10:196(1997)
2. Hokama Y, Nakamarua RM. Journal of clinical Laboratory Analysis 1: 15 (1987).
3. Kindmark C-O. Sacnd. J .Clin. Lab. Invest. 29: 407(1972).
4. Vaishnavi C. Immunology & Infectios Diseases 6:139 (1996).
5. Winkles J, Lunec J, Deverill I.Clin Chem. 33:685 (1987)
6. Tietz Textbook of clinical Chemistry, 3rd Ed. Burtis CA, Ashwood ER .WB Saunders Co., (1999).
7. Adam A, Ers P, Herman G, Stan JL.J.Clin.Chem. Clin Biochem .23:787 (1987).
8. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

9. Le Carrer D,Giraud F ,Siramy M,Bataillr R. Feuilletts de Biologie .34:39 (1995).

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	Catalogue Number		Temperature limit
	<i>In Vitro</i> diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry